VALIDATION OF DECOMPRESSION TABLES

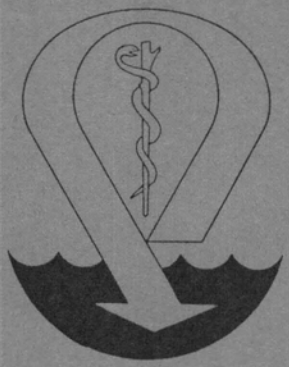
Thirty-Seventh Undersea and Hyperbaric Medical Society Workshop

Chairman

Heinz R. Schneiner

Editors

Heinz R. Schreiner
and
R.W. Hamilton



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The 37th Undersea and Hyperbaric Medical Society Workshop

VALIDATION OF DECOMPRESSION TABLES

Chairman: Heinz R. Schreiner

Edited by

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Proceedings of a workshop held 1987 February 13-14
at Bethesda, MD

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PREFACE

This Workshop was part of a broad program of technical grants, contracts, and workshops to provide support information for the activities of the NOAA Undersea Research Program, U.S. Department of Commerce (NURP). This Office supports a variety of undersea activities dedicated to exploration, conservation, and responsible exploitation of the coastal zones and the outer continental shelf. In supporting manned undersea activities one of the needs is for improved decompression procedures, and the NURP office is occasionally involved in assessing or even developing them. Like everyone else in the decompression business NURP occasionally faces the question of how to move tables forward through the various development and validation steps. The Workshop was convened to bring together a group of experts in many perspectives of decompression technology to address this issue. It was carried out under NOAA Grant NA82AA-D-00043 from NOAA to the Undersea and Hyperbaric Medical Society. The UHMS expresses its gratitude to the NURP director, Mr. Elliott A. Finkle, who was responsible for the contract and who participated in the Workshop, and to the current NURP staff including especially Dr. David B. Duane and Dr. William S. Busch.

Because of the impact of regulations and the legal climate on the validation issue and to help get the most mileage from our limited budget it was originally decided to focus on this problem from the North American perspective and not to try to make it an international Workshop. It was our good fortune that we did have the benefit of several important contributors from Europe, but we regret that we were not able to include several other of our international colleagues in this specialty who would have made it even better.

A word about the format of the Workshop. It was organized as many others, with speakers invited to cover topics and address specific issues in short presentations which were followed by discussion; they were given a list of topics to discuss and questions we hoped they would address. We asked for manuscripts to be submitted at the time of the Workshop, and most speakers did this; the requested wide 2-column format was awkward, and we apologize for the extra trouble this may have caused. Other attendees who professed to have some organized thoughts were invited to make a "mini-presentation." The entire proceedings was recorded by a court reporter, a transcript was prepared, and discussions were edited and included. When a speaker said something in a presentation that was not in the printed paper this is included as "additional comments" after the paper. Some of the talks were taken from the transcripts.

We apologize for the long delay in publishing the proceedings. The blame is accepted by the co-editor (RWH) who insisted on doing the production and was intimidated by the two-column format, in addition to having the usual conflicts that confront volunteer work. Fortunately, the topic is still as timely as it was at the time, and the value of virtually all of the material has not been swept away by subsequent events. We thank the UHMS staff, Dr. Lee Greenbaum for a discrete mixture of patience and gentle prodding, Buffy Jabine and Denyse Moore at the organizational level, and Ann Barker for pulling it together at the end.

The production, except for the manuscripts submitted as camera ready, was done by Hamilton Research, Ltd., using WordPerfect 5.0 and a HP Laserjet II with Bitstream Dutch 11 pt as the primary font. We thank Eileen Whitney for perseverance in formatting the text.

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INTRODUCTION BY DR. GREENBAUM

DR. GREENBAUM: I would like to welcome all of you to the facilities here on behalf of the Undersea and Hyperbaric Medical Society. I would like to thank all of you for coming, especially because each one of you is giving freely of your time without personal compensation. The Society and the diving community are most appreciative.

I would also like to thank NOAA for its support and its foresight in supporting this kind of a workshop, one which will be very helpful to the civilian diving community.

INTRODUCTION BY CHAIRMAN SCHREINER

We are gathered here to talk about ways in which to validate decompression tables. That is the manner by which one could determine a particular decompression procedure to be safe and effective. We are not here to talk about the development of decompression tables. We are not here to talk about decompression theory, although this is very near to my heart and I will manfully abstain from comments in this direction because the purpose of our gathering is to see if a consensus can be formed as to how one would recommend a validation of a decompression procedure, no matter how derived.

We also should talk about what safe decompression really is. Please focus on these twin objectives: What is safe and how do you validate it.

We will try to define what is currently accepted practice. We will, hopefully, formally or informally, review available approaches to validation, discuss and argue over options available to us to do such validations and, most importantly--and this is the goal we must be driving at--to see if this group can come up with a consensus statement. That would be well worth the trip for all of us.

MR. HADDEN: Yes. Excuse me. I am David Hadden with the Occupational Safety and Health Administration and I have been sent here to be an observer. I am wondering: are these protocols for this effort such that it would be usable for all people or just Naval-type personnel?

CHAIRMAN SCHREINER: You will find that very few of the participants are actually Naval personnel. The preponderance of the people here are from academic, commercial, civilian and governmental institutions, as well as the Navy.

INTRODUCTION TO THE WORKSHOP: BACKGROUND HISTORY AND SCOPE OF DIVING TABLE VALIDATION

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In the beginning God created the heavens and earth. It was not necessary to create the oceans, it was raining at the time. He neglected, however, to devise decompression tables that Adam and his descendants would require. They would need them, so they have been trying ever since to do it themselves.

The scope and complexity of procedures now used in modern civilian and military diving belies their simple and common origin.

As practical working diving with the full body diving suit began, about 1840, the gas pumped to the diver, by human power, was air (1). Use of compressed air to aid in tunneling occurred at about the same period (2). After the extensive experience gained in many nations, over more than 100 years, it is now the purpose of this conference to consider how procedures used for modern and future diving and decompression with air and other gases should be validated as reasonably safe for operational use. The major reason these validations still remain to be devised, after a hundred years of diving, is that recent successes in research, and their equally successful applications to expand diving operational capability, have together opened still further opportunities for improved durations, safety and effectiveness in diving at all depths. Opportunities very soon become requirements, and modification and development of diving procedures has for both reasons expanded greatly during recent decades. However, quality and systematic validation has not kept pace with this expansion of "tables" and this operational use.

Evolution of diving table validation

As diving began, decompression sickness was recognized in the laboratory, but not by the working diver (3; 1). The fact of human decompression sickness had to be discovered as a consistent consequence of decompression following excessive exposure to compressed air. Initial efforts to avoid decompression sickness were based entirely upon empirical validations of procedure, seeking avoidance of overt symptoms or signs. At the advanced present stage, in spite of the now established recognition of decompression sickness as a complex of systemic effects, validation still depends essentially entirely upon the same symptomatic indices as were observed in the beginning.

At first diving itself was trial and error. No tables existed, and therefore no validation of tables was practical. The origins of table (procedure) validation were simultaneous with the evolution of reasoned concepts concerning the cause of "bends", and concepts concerning the degree to which tissues could sustain excess pressures of dissolved gas without forming gas "bubbles". These concepts were based upon early and astute recognition of what appeared to be patterns 19of exposures in bends-producing circumstances (4).

Origins of validation in naval units

The earliest systematic tables susceptible to follow-on validation arose in 1906-1907 from the British Admiralty experiments, guided by Haldane and his associates (4; 5). These showed that an air breathing diver could "with reasonable safety" tolerate a rapid change from a high absolute pressure to a proportionately lower absolute pressure (e.g. if the ratio of high to low absolute pressure did not exceed 2.3 to 1). This was the first step in the origin of the "stage" decompression method. The concept derived *from exploratory trials in pressure chambers and from experience in working dives.* While this concept formed the basis for much of early air diving table development, empirical validations of the limited depth/duration tables based upon it were not in fact real validations of the concept, since the concept does not pertain over the larger range of diving exposures subsequently experienced.

The next phase in evolution of need for diving table validation was almost immediate, superimposed upon the highly effective stage method. It

involved the fundamental conception that in diving and decompression, there occurred an exponential uptake and elimination of inert gas, at different predictable rates in undefined different tissues. This farsighted concept provided for rational mathematical determination of the duration of stay required for inert gas elimination at the stages of decompression (4). Here the actions of validation were by *trials after conception.* The principle itself remains a key element of all diving table development and evaluation.

Entry of the U.S. Navy into extensive diving table development and trials began only a few years later, about 1912, expanding use of the above mentioned dual concepts to air tables validated by empirical exposures to air pressures equivalent to 300 feet of sea water, and used to that depth in the open sea (1). The validation, again aiming for "reasonable safety", was accepted with a bends incidence as great as 5%.

From these heroic efforts, in these two countries, spanning thirty years, came the foundations of understanding supporting most of what has followed. In no sense were these early developments or validations "trial and error". Exploration was by exceptionally informed and imaginative individuals, deriving brilliant concept from observations, performing planned test of concepts, and doing so without benefit of electronics, modern medicine or computers. The numbers of trials and diver subjects used in such air diving validations were massive (1; 6). Prior to World War II the development and then redevelopment of naval air and helium diving tables were directed to perceived naval requirements, not to industrial or sport diving. Civilian diving has utilized the results for relatively shallow diving without investment or modification, even to the present time.

These same extensive empirical validation methods used for naval air diving, progressively were used in parallel in naval laboratories to explore diving with *helium-oxygen mixtures* (7; 8). In Britain and the U.S. *oxygen limits* were explored to provide for facilitation of inert gas elimination in final stages of decompression (9; 10). Tests in large numbers of diver-subjects in experimental diving units and diving schools explored the validity of *surface decompression for air and for helium-oxygen diving* (11). The result of these many hundreds of exposures, largely in U.S. and British Navies, over the period into and soon after World War II, provided the reference against which additional tables could be derived for the later great expansions of commercial and military undersea activity.

Changes in naval activity following World War II

In the decade immediately following World War II gains were made in concept and validation through improved technical communication among countries, the introduction of new methods of self-contained diving into military operations, and the extension of basic and applied undersea research by universities. Close international interaction of military and university interests derived from establishment of scientific and technical groups such as the Panel on Underwater Swimmer Technology and the related Underwater Physiology Symposia (12). Active efforts to further improve air diving tables and develop repetitive air diving tables were carried out, with transition from "by hand" computation to use of the earliest electronic computer to speed revision of tables between different test dive series (13; 14; 25; 15; 29). Emphasis upon use of self-contained diving for purposes of undersea explosive ordinance disposal presented requirements for development and validation of tables for nitrogen-oxygen and helium-oxygen mixtures, applicable to rebreathing systems (16).

To about this point, the early 1960's, the procedure used for practical validation continued to be the exposure of large numbers of diver-subjects to determine the incidence of decompression sickness "requiring therapy". The acceptance of degree of risk was relevant to military use, in operations under direct military supervision.

The brilliant proposal of "Saturation Diving", initially with helium and then with nitrogen, drastically modified the philosophy of validation (17). Saturation diving entered into military and civilian use with tests in only a few subjects. A special stage of evolution had arrived when, in the relatively simple circumstance of saturation, concepts of tolerable excess inert gas in tissues appeared to provide a partial substitute for large scale testing. Eventual recognition that greater degrees of excess gas partial pressure can be tolerated at higher ambient pressures (18; 19; 20; 21) resulted in return to systematic test and validation in large

subject numbers, to establish limits for deeper and shallower excursions from saturated states (21). These studies and the resultant practical procedures were probably the largest practical advance in the past 80 years.

Expansion of civilian research and industrial interest

The mid 1960's also were the beginning of modern commercial diving. Three concurrent events rapidly extended forms of operational diving and its related table derivation beyond the capabilities provided by the painstaking naval developments. These events were: increasingly easy access to electronic computers, massive expansion and success of undersea biomedical research, and the astounding engineering developments accompanying the search for offshore petroleum.

While diving for sport expanded in popularity in parallel with expansion of industrial diving, it has been restricted almost entirely to the limiting durations involved in use of open-circuit air breathing and has therefore largely tended to utilize established air diving tables. No special new validations have been involved.

Development of the modern commercial diving industry paralleled biomedical research, after beginning with the naval diving tables then available, and most recently revised and tested. Then, competition in carrying out the demanding, deep and prolonged work of offshore diving, in remote regions and severe weather, led to need for tables to depths and durations previously considered "exceptional". The existing tables had unacceptable incidence of decompression sickness, and some have not yet been improved. Technologically advanced diving companies and universities devised new helium-oxygen diving tables; some tables utilized low concentrations of nitrogen in the helium-oxygen mixtures to modulate the adverse effects of helium upon speech communication, and some included the use of air and oxygen to speed elimination of helium (22; 23; 24).

Procedures for such special developments have, with almost no exceptions, *depended upon use of a reasonable concept, with limited trials in laboratory chambers, and slow accumulation of imprecisely documented operational experience.* The more common path, employed by diving industry generally over the past twenty years, has been the uncorrelated adjustment or modification of naval or other existing tables by measures intended to reduce bends incidence below that considered related to an original version. Some of the modifications are clearly sensible. However, validation by large scale test of such numerous and unsystematic, superimposed alterations has not occurred and is not practical. Validation through subsequent operational use is handicapped by lack of adequate documentation, except in a small number of companies which have maintained the detailed record systems required.

Naval units still retain the opportunity for extensive and systematic empirical validation, as exemplified by the important helium saturation-excursion tables cited above, and others. However, large developmental advances have occurred through research in universities and other government agencies, leading to multi-year commercial operational use of new tables involving helium saturation, nitrogen saturation, helium-oxygen bell diving, air and helium-oxygen surface decompression, and nitrogen-oxygen diving. Such development often utilizes retrospective analysis against prior documented experience. However, the original approach to validation by extensive laboratory trial is not usually performed and is impractical in view of the expanding scope of diving.

This is the dilemma that has made this Conference long overdue. The Summary Tables included here indicate the scope of the task, and the need for simplification.

The scope of the existing practical problem

Diving for its numerous purposes and in its many forms is no longer performed against a single set of "standard" air tables, or helium-oxygen tables. The obvious requirement for validation or consensus for diving/decompression procedures safety cannot be standardized as a "Validative Procedure" for all diving, because of (a) the presently desirable multiple forms of diving, (b) the extreme ranges of depth and duration, and (c) the peculiarities of operational purpose. The figures which follow illustrate the need for a broad, adaptable and informed policy of validation, based upon use of existing information, informed judgment, reasonable laboratory exploration, improved statistical methods (27), and improvements in per-

Table 1. Forms of diving/decompression (gases optional)

- Single depth excursion from surface.
- Repetitive single depth excursions from sea level.
- Repetitive diving at high altitudes.
- Saturation exposures.
- Deeper and shallower excursions from saturation.
- Flying after diving.
- Multiple level diving.
  - Successive shallower stages.
  - Random depth.
- Decompression following therapy.

Table 2. Breathing gases as factors in decompression evaluation.

- Oxygen.
  - Pure O_2 diving.
  - Uses in any diving gas mixtures, in any form of diving.
  - Uses in any decompression.
- Air.
- Single inert gas-oxygen mixture.
  - N_2-O_2, He-O_2, Ne-O_2.
  - Fixed or changing % composition.
- Dual inert gas-oxygen mixture.
  - N_2-He-O_2, He-H_2-O_2.
  - Fixed or changing % composition.
- Sequential alteration of inert gas.
  - In compression (e.g. Air, He-O_2).
  - In decompression (e.g. He-O_2, N_2-O_2, Ar-O_2).
- Composite (multiple depth, multiple inert gas, inert gas sequencing, oxygen pressure sequencing).

formance of extended operational trials.

The scope of the task is illustrated by the many *forms of diving/decompression* which now exist, encompassing at least the range in Table 1, from a single shallow air exposure to deep, multi-day saturation-excursion, to multiple-depth diving of various forms.

Breathing gases are usefully varied to provide improved range or safety (Table 2). The imaginative use of the respirable gases and mixtures has

Table 3. Recognition of ancillary factors in diving/decompression

- Compression (degree, rate).
- Immersion.
- Water temperature.
  - Effects via body surface.
  - Effects via deep organs, tissues and sensors.
- Body heating.
  - Body surface.
  - Respiratory tract.
  - Deep body.
- Isobaric counterdiffusion.
  - Superficial (ambient/respired).
  - Deep tissue (gas sequencing).
  - Combinations.
  - Relations to decompression.
- Gas density.
- Work (nature, degree, duration, rest cycles).
- Strain (force application).
- Circulatory impediments.
- General physiologic status.
  - Hydration.
  - Cardiovascular fatigue.
  - Endocrine.
- Environmental/equipment factors.

opened industrial, military and scientific diving.

Ancillary factors of the diving environment, operational requirement, engineering, or work functions (Table 3) overwhelm the isolated validation of "models", and must be incorporated in every overall validation. For essentially none of these ancillary factors has a validation been accomplished.

Philosophies of validation (Table 4) have been different among pioneering groups and agencies, and will benefit more from sensible correlation, rather than from rigid selection of any single method.

The relative importance of individual component factors in practical diving/decompression validation (Table 5) has in no instance yet been defined, and may not be. This emphasizes the requirement for versatile validation procedures based upon intelligent consideration of the multiple factors concerned, in the multiple diving methods, and multiple purposes for which they are employed.

Table 4. Philosophies of evaluation methods

- Retrospective analysis of prior experience.
- Stepwise empirical (not trial and error).
- Mass testing.
  Naval (international).
- Selective testing.
- "Statistical" validations.
  Laboratory--number of acceptable trials required = ?
  Operational--number of acceptable trials required = ?
- Integrated operational "experience," incremental adjustment.

Table 5. Relative importance of factors in evaluation

	Probable Importance
♦ Evaluation of choice of discrete "model" for inert gas solution and release from solution.	+
Has least influence in an ideal subject, in ideal dive condition, and in a poor subject in complex conditions.	
♦ Temperature factors evaluation.	+++
Direct local and deep influences, secondary neurophysiologic and hormonal/transmitter effects, circulatory reflex effects.	
Influences of protective measures.	
♦ Inert gas sequencing evaluation.	++
♦ Evaluation for optimal use of oxygen.	+++
Degree, sequencing.	
Physiologic, toxic effects.	
Therapy reserves	
♦ Intelligent blending in evaluation.	++++

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DISCUSSION AFTER DR. LAMBERTSEN

DR. BENNETT: I do not know whether it is possible to explain why, but it seems that we have got ourselves into a situation where we are not testing tables properly. Is it because we do not have the mechanics or we do not have the money? Do we not know really how to do it properly, or is it a financial reason that we just can not amass a big enough study?

DR. LAMBERTSEN: What I was truly trying to do was not to just give you a matter-of-fact history, but to crack the thumb a little at the beginning to have you see that there are probably, in that short summary I gave you, several hundred

tables. If the Navy has used several thousand subjects for one table, which it has done (the British Navy and/or the U.S. Navy), no one is going to use several thousand subjects for tables from now on. I am not trying to close your meeting. I am trying to turn your question, though, away from money. It does not make any difference. If we paid you everything in the world, you would not spend your time like that. You would not be able to. It would not happen. Is that an answer? I do not think it is money. I think it is that new methods should be used.

NOAA'S NEEDS AND CURRENT APPROACH TO BRINGING NEW TABLES ON LINE

J. Morgan Wells, Ph.D.
NOAA Diving Program
National Oceanic and Atmospheric Administration

This talk briefly covers some of NOAA's plans, and our projected needs and approaches.

First of all, I apologize for not having my written text here. I noticed not many people had theirs, but I will bet I have the best excuse in the house. You see, my house burned down two weeks ago, completely to the ground, melted my outboard motor into a pool of molten aluminum, and I have not been able to find the text since. I'm sure that it was in that house. That's a true story.

Let us look at our existing trials and tribulations. NOAA is a pretty small outfit. We have about 300 divers. Generally, we are considered shallow-water divers; however, our average dive is deeper than the United States Navy, according to statistics, about a foot deeper. The Navy dives average about 46 feet. I think NOAA dives average about 47 feet, usually for half an hour. So you can see in our organization we are not talking about deep, long dives. We do some saturation diving, but very little is in-house. A lot of it is supported through grants to universities, and so forth. Some of the people in this room work on NOAA contracts in that area.

For our standard problems we train a lot of people, run a lot of people through recompression chambers, and some existing schedules still give us problems. These are air exposures in an air-filled chamber. That problem is not licked yet.

Our principal applications, however, are in no-decompression diving and repetitive diving. Each year, the need or the requirement for multiple dives seems to become more important in our operations. So, not just extending no-decompression limits or decompression diving on a practical sense, but repetitive diving--both surface based and from shallow nitrox habitats--keeps emerging as an important area, one where we have some needs.

For gases other than air, mixed gas, normally we talk about heliox. In our case, we are looking almost completely at "nitrox" [or "enriched-air nitrox," Ed.] diving. We have developed, and tested some years ago, some 32% nitrox mixtures, a mixture that has had limited use but provides great advantages--not only in extending no-decompression time, but we have discovered through its use that it has hit on one of the areas that was our greatest need. This is repetitive diving. Nitrox--enriched air--has tremendous advantages in meeting our needs in the area of repetitive diving.

Regarding saturation and saturation excursion diving, this meeting has brought together some of the people working in this area. We are working toward incorporating some of the work that Bill Hamilton and Russ Peterson and Bill Schane have been doing into our new manual. It is obvious to us all that we certainly do not have the final answers on shallow-water nitrox saturation with multi-depth excursions and repetitive excursions.

The problem is a complex one because of the tremendous variation in the way we desire to do things and theoretically should be able to do things. This presents a very complex validation problem, in my opinion. This applies not only to excursions, but to the final saturation decompression and the relationship of the final decompression schedules to the previous history of pressure and gas exposures.

Of the things under consideration at this time, nitrox is our most promising child in this area. We are looking for diving to depths generally less than 150 feet and, believe it or not, application of nitrox mixtures in the 60 to 100 foot range where at least our computers tell us that we can make tremendous headway, spending four times as much time during the course of a working day, again through repetitive procedures, than we can with air. And this meets our operational mode quite well. We've spent a tremendous amount of time in the 50 to 100 foot range. So, we are looking into new gas mixtures in the 30 to 50% oxygen area.

In saturation diving, things under consideration that we've been knocking around with our experts

are multi-gas exposures, with gas switching on excursions that may potentially offer some significant advantages. An example would be switching from nitrox to heliox for deep excursions from nitrox saturation. This is a whole area that looks fruitful, and the computers tell us it will work in a lot of cases. Again, it will be tough to test.

Oxygen toxicity remains a problem in this area, both pulmonary and CNS. We know oxygen has tremendous potential in helping us out of decompression situations, but we are still titrating it, tickling the edge on where we can use it, in recent years we have been--what is it the astronauts say?-- "Pushing the envelope," with respect to pulmonary limits.

In the future, I think we are going to remain in the reasonably shallow water business--less than 200 feet. Spending very long times and especially repetitive diving will be our priorities.

What is our approach? Testing must be done. We have seen too many cases of immediate application of tables. No one in this room, of course, does that.

Peter Bennett asked a rather important question there about dollars. You know, I'm from the government and we get everyone's taxes, but we are still not rich. As those of you who have been sending proposals to NOAA that have gone largely unfunded, you must realize that we do not have an unlimited supply of dollars, and yet we seem to have an unlimited thirst for new information. These do not seem to be quite compatible. Computing of tables is getting much less expensive than it was 10 years ago. Testing of them, I do not think is any less expensive. It, perhaps, might be more than it was and more difficult because use of human subjects is becoming more difficult. A lot more difficult than it used to be. And the injuries resulting from them have significantly more serious consequences.

DISCUSSION FOLLOWING DR. WELLS

CHAIRMAN SCHREINER: Your agency is clearly interested in having available reliable procedures for dives in the depth range and the general envelope of conditions you have outlined. Are there criteria in your agency that can be used to determine if a particular diving scheme or decompression scheme is reliable?

DR. WELLS: We have nothing you would call fixed standards. We try to conform as much as possible to what we might call by the vague term "industry standard." So, each one is on an individual case-by-case situation.

CHAIRMAN SCHREINER: In keeping logs of such dives, what is used to characterize the outcome? In other words, there are many end-points of decompression that could be viewed as indicative of reliability from the obvious diver-reported symptoms all the way to long-range effects, perhaps. Where does your agency look for an endpoint? On the first level, by this I mean the reported symptom level, or does the agency go beyond that in long-term follow up? I am talking about operational diving.

DR. WELLS: In the latter case, the long term effects, I think we have actually become lazy, as have a number of people. Or perhaps we were chasing a non-existent situation--the long-term effects of inadequate decompression, aseptic bone necrosis, and so forth. We went through a spike, as did a lot of people in this country, of monitoring this carefully. We simply do not do that anymore.

Operationally we train our personnel quite well in their basic training, in recognition of subtle decompression sickness. So, in recent years, we have had a lot more reported, but they have not been all that serious. That, I think, is more a matter of training of the individuals in recognition of subtle decompression sickness.

I am still not answering your question because we do not have a hard and fast rule about the endpoints.

CHAIRMAN SCHREINER: I just wanted to see what your agency views are, for example, if an operational dive regime yields a particular outcome, be it DCS, be it bubbles, be it something else, at what point in time does the agency say, "This particular regime is not acceptable. We have to do something about it."

DR. WELLS: I think we do not really have an agency policy on that. When we develop something like this, it is usually through a contractor. A lot of them are sitting in this room. And, generally, they will tell us. It is usually obvious to both parties if there is a problem.

DR. HAMILTON: You said the 32% oxygen tables were tested. Would you tell us how you tested those, and also would you tell us how you came up with the protocols for use with that gas mix?

MR. IMBERT: You say that you prefer "nitrox" [enriched air] diving. On what data do you support such a statement? Would you think that using oxygen would have the same effect, or do you have an explanation as to why nitrox is better for repetitive diving?

DR. WELLS: Okay, a little bit of history. For our first 32% tables we started using the simple concept of equivalent air depth, straight across the board. In those, of course, we can use the USN repetitive groups because we are basically equating the nitrogen in the breathing gas to that of air. So, life is very simple if one believes in this concept of equivalent air depth.

Bill Hamilton asked about the testing of this. It was done a number of years ago. In 1977, the initial ones, were in dry chambers. Very little testing was done on repetitive dives. We were looking, at that time, at maximum no-decompression limits. If you are interested in our testing of the EAD (equivalent air depth) concept with respect to repetitive dives, we actually had none in our tests. I think other people here might comment on the adequacy of this concept.

Now, in our future ones, we are at least computing them from scratch, using the U.S. Navy model and comparing that against some of the existing models. What do we call the models that you people use, "Privileged models? Secret formulas?" We plan to be testing later this year; that is why I am so interested in the outcome of this meeting.

CHAIRMAN SCHREINER: Give us a feeling, if you could, for the number of dives that are being performed in your agency per year.

DR. WELLS: It has been almost constant over the last six years at approximately 6500 dives per year, by our 300 (more or less) divers. The number of active divers varies between 250 and 300. Some years ago, this was almost exactly 10% of what the U.S. Navy reported. I think we are less than 10% now.

CHAIRMAN SCHREINER: What proportion of these dives were done by female divers?

DR. WELLS: By female divers? I am going to take a guess; about 5% of our divers are females.

DR. ARMER: From what Morgan is saying, I see some problems that we have in talking about what criteria the Smithsonian would accept for new tables, what criteria would be usable. We have about 100 full time employees who are divers at any given time (not full-time divers). They already know that the Navy tables are not applicable to shallow repetitive diving of the kind we do. So, they just kind of take a very conservative guess and dive. Or they assume that if they stay under 30 feet, shallower than 30 feet, it does not matter how much time they spend. We are beginning to find out that this is not true. We have divers who dive four to six hours a day for a year and those kinds of divers appear to accumulate some nitrogen. They do, occasionally--rarely, but occasionally--get mildly bent. Interestingly enough, at the aquarium--which is only 27 feet deep--there are 10 divers who are diving four to six hours a day. Although they do not get bent very often, what happens is they will dive once or twice on the weekend and then come back to work and get bent on Tuesday. So, obviously, they tipped themselves over on the weekend.

The problem is that I do not think we have gathered the kinds of statistics that we would like to have. We need tables to guide us in this sort of shallow-water repetitive diving. The acceptable percentage of bends cases would be zero. But, at present, all we are doing is just sort of getting along.

DR. WELLS: I would like to address Mr. Imbert's question about oxygen and tell you something you may not realize is going on. The introduction of the Canadian DCIEM tables is rather

a blessing for a lot of us. But they are actually causing some trouble for very unexpected reasons. Innovative and not too bright American recreational divers look at them and pick the good parts and omit the bad parts, and we see these people at our treatment chambers.

They are hybridizing their in-water oxygen, etc., with the United States Navy tables to come up with the table that looks best to them. Two problems are resulting from this; decompression sickness and oxygen toxicity. Some of these people dive very deep and use in-water oxygen stops comparable to the DCIEM tables. We have treated people that have had CNS oxygen hits after long deep air dives using inwater oxygen. People are hybridizing these tables and getting into trouble with it.

MR. HOLLAND: I agree with your comment about hybridizing decompression tables; it does not only happen in the recreation industry. (Unfortunately, we have trouble with some of our old and bold who know better.) I would like to ask, in terms of what you are looking for at the end of the day--safe tables-- could you give us some idea of the incidence of DCS you have across the board, and in any particular area? You must have in your 6500 dives per year, a rough DCS incidence which would give us a target with which perhaps we should aim to come below.

DR. WELLS: You might have trouble beating it. A rough guess is, we have recorded between only 3 and 5 cases per year out of the 6500. That is over the last decade.

DR. SHANE: To comment on Morgan's numbers, because we view ourselves as a part of NOAA at the St. Croix facility, we do about 10,000 saturation man hours a year of which about 20% are females, and we have had about one case of decompression sickness a year. I am talking about shallow water, a 47-fsw saturation mission of 7 days.

DR. KINDWALL: Morgan, I would like to comment on the number of dives and the intrinsic problem with Navy or "water" diving tables. If the tables are set up for every 10 feet of depth, (30, 40, 50, 60, essentially) only one dive in 10 actually does a "face-value" test of the tables. So, in terms of running your tables out to test their validity, you probably only made about 650 dives which you really could look at.

DR. WELLS: Yes. I think we would have even less. If I remember Peter Edel's block, it is 1 out of 100 because they are 10 feet and 10 minutes. So, you are somewhere between the upper right-hand block and the lower left-hand block.

DR. KINDWALL: I guess we would divide it by another 10. Then, would you have 65 "face valve" cases on the average?

CHAIRMAN SCHREINER: I think what this illustrates is that decompression procedures are boundary conditions and that actual decompression occurs generally within those boundary conditions. But even with 6500 dives, can one say that the procedures that your agency uses are generally recognized as safe or is that an over-statement?

DR. WELLS: We certainly consider them safe or we would be out of business. Our need in this area really is to increase operational effectiveness and we would like to do this through new methods, especially mixed gas methods. I am a little bit bashful and becoming more bashful by the year; decompression sickness, at least in our outfit--is becoming more serious today than it was a decade ago. Lots more people are looking at you.

So, our principal drive is to increase operational effectiveness through the use of different tables, ones that have a greater theoretical potential, but we really can not afford to make mistakes in the process.

CHAIRMAN SCHREINER: Okay. So it is a joint requirement to be safe as well as effective.

DR. BENNETT: Can I ask if you use any of the diver-carried computers that are on the market today?

DR. WELLS: We have some. We are even testing reliability of some right now. We do not use them operationally.

CHAIRMAN SCHREINER: Now let me come back to two points, if I may. One is the record keeping of your thousands of exposures every year. How is that done? Is there a centralized place in your agency that keeps logs?

DR. WELLS: Each diver submits a log. It comes in to my office here in Rockville and is put into a computer. We have breakdowns, by both depth and time. We use atmospheres, time in minutes and we break down the percentage of our dives. So we have rather decent records on depth-time combinations.

CHAIRMAN SCHREINER: Is this data base available to the public?

DR. WELLS: Anyone that wants it. Do not put that in *Pressure* please, because as soon as we make an announcement like that, the letters come in from all the sport divers and teenagers all over the country who are writing term papers.

CHAIRMAN SCHREINER: I understood 20% in Bill Shane's operation are female, I believe; is that correct?

DR. SHANE: Yes, sir.

CHAIRMAN SCHREINER: Are there any physiological or special considerations? Are there decompression allowances made, particularly in cases of pregnancy or with regard to anatomical and physiological differences, or are they ignored?

DR. WELLS: The only sexist thing we do in that area is provide the women with special diving suits.

DR. SHANE: We do not permit pregnant ladies to dive.

DR. WELLS: Correct. That is also for the in-house NOAA people.

DR. ELLIOTT: I think we have not quite answered the first question yet, that about the validation of dive computers, the diver-carried decompression computers. Do you see that as being within the discussion of this group? I imagine the answer should be yes.

DR. WELLS: Yes. You took the word right out of my mouth.

DR. ELLIOTT: And secondly, Heinz has touched on this question of what do we mean by "validity." Chris said, "5 percent incidence was the original basis." Well, we may have reduced the percentage, but what is bends incidence? Are we referring to reported symptoms, or are we referring to something which depends upon the judgment of a doctor or a dive supervisor, or perhaps the number of recompressions, and is that, indeed, a correct measure of the validity of a table? I hope others will address what they mean by "validity" in their presentations.

Associated with that, we have the problem in the North Sea of an alleged severe prevalence of Type 2 DCS when diving beyond the Old World Navy Limiting Line, and I think, therefore, that one has to talk about the validity of different depth-time duration parts of the table. To give an overall incidence of virtually no bends out of thousands of dives, I think, may be meaningless.

And then, finally, you are dependent on the feedback you get from your divers of the number of bends, etc., they had, and you file logs. Now, I am not saying that NOAA does this, but it is alleged that a dive log written after a bend is not necessarily valid, and therefore I would like to suggest that compliance assurance with decompression procedures is something that we should check. I think a lot of the bad words said about some decompression tables may be due in fact to the divers not having used the table properly, and the poor old guy who generated the table gets the stick, but it is not his fault.

DR. YOUNGBLOOD: Do you not realize that the American government uses polygraphs when they debrief their divers, in your example.

DR. WELLS: A couple of comments there. We are quite interested in the development of diver-carried decompression computers, but again rather cautious about the reliability of such things.

Also, I did not mean to imply that there are problems with existing standard tables. Our desire, and a very strong desire, is to increase operational effectiveness, which means new tables and testing them. We are getting more reports of subtle

decompression sickness, a lot more than we got a decade ago because the guys 10 years ago would just sweat it out and they would go away. We really hit it hard in our training. The divers, now, are reporting some of these, at least with greater frequency than they used to. But perhaps not all of them are being reported.

MR. GALERNE: It is more equipment than anything else. In our organization, we have systematically recorded on paper thousands and thousands of dives. And a few times, we find, you know, the bends occur after a normal decompression. But also we find something which I do not like, but we cannot raise that here. Some divers do not seem to be able to take regular decompression. Some divers are difficult to bend and some are very sensitive. And, often, you have the same accident on the same table with the same man and with nobody else. So, I suppose somewhere in the physiology of the man there is something that we do not know which makes him very susceptible.

DR. ARMER: It seems to me there are two tremendous inaccuracies of collecting data here from NOAA divers and my divers. One is, we really do not know very much about the log of the depth of a particular dive because they are working during the dive. They may say, "I dived to 40 feet," but what they mean is over a two-hour period that was the deepest they thought they went, but their dive actually was up and down and all over the place so that it is very, very inaccurate. But there is a gadget that the Japanese [Dr. Nashimoto, Saitama Medical School. Ed.] now have, that will log a dive accurately and store it in a little computer. I believe that is going to be available or is now just available.

The other thing is, we are getting better, too, in reporting bends incidents. I recently find in my annual exams that if I question enough I will find what appears to be a history of a minor problem that otherwise would never have been mentioned. So, the true incidence is very hard to get.

DR. ELLIOTT: Could I just pick up that point about depth/time recording? There is, actually one which is available; it was developed in Norway. It has got a 200 hour recording duration, taking samples of the time and depth. It was evaluated by the Norwegian Navy, and currently we (Shell) are using it on one of our single-buoy moorings (not in the North Sea, but on the other side of Britain) where we have year-round surface decompression diving at 140-170 feet. We are evaluating these records at the moment and it seems to be working very well. After the dive, these data are downloaded into a minicomputer; you can collect lots and lots of dive data in this manner.

We are doing this as a development. We will certainly keep it in the picture. I want it in the record because the problem has been mentioned, and I think it is one way you can assess decompression compliance and, therefore, the validity of operational tables as used.

CHAIRMAN SCHREINER: Well, I think this is very germane because it has been very clear for the last hour that experience is the foundation of decompression safety and validation and the accuracy with which these experiences are recorded obviously affect the validity of the base on which we proceed.

EXPERIENCES ESTABLISHING DECOMPRESSION PROCEDURES AT NSMRL

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U.S. Naval Submarine Medical Research Laboratory

The United States Navy policy for the promulgation of new decompression tables follows a well defined pathway (Table 1). Following research efforts to develop new tables or modify existing ones, the proposal is submitted to the Commander, Naval Sea Systems Command for the attention of the Supervisor of Diving, via the Navy Experimental Diving Unit. If the proposed table or modification is found to be valid by the Experimental Diving Unit (they are tasked with table development and modification by the Navy) the Supervisor of Diving will assemble these proposals into numbered changes to the U.S. Navy Diving Manual.(1) These numbered changes also include information on equipment, techniques and procedures as they are developed.

USN SUBMISSION PATHWAY

1. Contributor of Decompression Table
2. Experimental Diving Unit
3. Supervisor of Diving
4. Commander Naval Sea Systems Command

Table 1. Pathway for submission and approval of new and modified decompression tables within the United States Navy.

When proposed tables are accepted for restricted use, for example in a pressurized rescue scenario, they will not be published in the Navy Diving Manual. Rather, the tables and guidelines for their use will be promulgated via message or instruction. Use of these procedures is then carefully monitored to insure they are employed only in the intended circumstances.

Naval Submarine Medical Research Laboratory (NSMRL) has followed traditional approaches to formulate usable decompression procedures. Investigators are trained in the classical methods of calculating decompression tables. They complete literature searches and consult individuals with government, academic and private experience in developing and testing tables similar to those desired for the task at hand. Frequently, proposed decompression procedures extend known limits sufficiently that preliminary animal work is deemed prudent prior to human trials. Following animal studies and limited human testing, tables that seem safe and practical are made available for further laboratory testing and emergency use in the fleet. Data gathered using these tables is recorded at the Naval Safety Center published by NSMRL and is available to other investigators for use in further table development.

For example, work during Project Genesis to establish safe diving procedures for saturation diving began with animal studies at Naval Submarine Medical Research Laboratory in 1957.(2) Proposed saturation decompression schedules for human exposures were calculated by Dr. Workman.(3) Initial human experimentation consisted of testing three men breathing helium at surface pressure for seven days, followed by the exposure of three men at 100 feet for six days before decompression, and ultimately by the exposure of three men at 200 feet for 12 days. These exposures were followed by exposing four divers to 300 feet for 24 hours. Two divers were exposed at 400 feet for 24 hours. Using these decompression tables, based on Workman's calculations, all divers emerged symptom free at the end of the decompressions.

The experiments then moved into the ocean. Sealab I exposed four divers at 193 feet for eleven days and Sealab II exposed 28 divers at 204 feet for two weeks or more. Only a 50 year old diver developed decompression sickness out of the 32 diver subjects. As in most decompression table development, the procedures developed for these decompressions were based on the best knowledge available at that time. The number of initial human exposures has frequently been small when examined by the statistical methodology developed by Berghage and Heaney.(4) With continued development these tables have enjoyed a reasonable degree of success. Recently a table for unlimited excursions from individual storage depths was developed by the Experimental Diving Unit, tested and approved for field use. It had reasonable, but limited, testing and after operational experience at Submarine Development Group One, the Navy mandated decreased magnitudes of allowable excursions. Ultimately a modified table was considered sufficiently reliable for inclusion in the U.S. Diving Manual.

Today, thirty years after Dr. Bond and his investigators conducted their early animal experiments, NSMRL is still using relatively few divers to test decompressions. It is adding data manipulation by powerful statistical algorithms, described by Commander Weathersby and his colleagues elsewhere in this workshop. These algorithms will be used to quantitate the inescapable risks of decompression sickness during the

emergency submarine rescue procedures we have been developing for over ten years. Those tables are the best emergency procedures currently available, but routine use of them will be allowed only after review by appropriate higher authority, field testing and training exercises generate the numbers of man dives necessary for statistical confidence.

All tables are associated with a finite risk probability and the scientist can define that risk probability, but real proof of safety of tables comes only at the cost of large numbers of data points... or in this case dives. Validating decompression tables requires development and laboratory testing based on, among other things, historical experience. Initial development, grounded in common sense and practical resource limitations must sooner or later give way to controlled field testing with adequate support in an operational situation. Feedback of data from the field and ability of the system to accept and promulgate modifications are essential. When a sufficiently large number of dives are accumulated, both the decompression theory and the tables based on it can be evaluated with some measure of statistical reliability. The end user of the tables can then make a choice as to what degree of risk is acceptable for any operational conditions. Those making such decisions must realize that the closer one approaches a decompression sickness incidence of zero, the greater the direct and indirect developmental and operational costs incurred. It is incumbent on the diving supervisor and those responsible for choosing tables for use to insure that the decompression procedures chosen are appropriate for the situation at hand. Tables developed for a restricted population may not be applicable to a general population. Environmental conditions and physical standards for specific divers and operations may differ significantly from those under which the tables were developed. The reliability of the tables may then differ significantly from published data. At present informed consent and assumption of some risk by the diver in return for a reasonable compensation seems the most sensible solution. The assumption of higher than normal risks may prove necessary under some circumstances. Thus exceptional exposure tables might be the only option to rescue a trapped diver or submersible. Even calculated but untested tables and procedures sometimes prove invaluable. One classic example comes to mind of the decompression of two divers who were trapped for 73 and 45 hours at 55 fswg when a barge hull broke and trapped them during salvage operations in World War II.[5] The concepts of saturation decompression were largely unexplored. However immediate recompression after their rescue and application of the concepts of Haldane of reducing the pressure to half and resaturating before further pressure reductions was life-saving.

The issue of informed consent to continue evaluation of decompression tables becomes critical when evidence of delayed pathology such as Dysbaric Osteonecrosis presents. Both divers and supervisors should be informed when tables have a low degree of long term statistical validation.

Urgency can often affect the degree of risk that is acceptable in a diving operation. Navy divers readily embraced decompression procedures with an accepted high risk to conduct rescue and salvage operations on the Squalus in 1939. Currently, the U.S. Navy Diving Manual contains not only tables for routine surface-supplied diving operations but also exceptional exposure tables known to carry a higher risk of decompression sickness. They are reserved for truly unusual circumstances. Indeed, the surface supplied Helium-Oxygen tables are all exceptional exposure tables for operations below 300 feet beyond which, for routine operations, saturation diving techniques are used almost exclusively. High costs, the emergence of successful saturation techniques and the dictates of statistical validation have simply made it impractical to conduct the number of test dives that would be required to improve existing surface supplied tables in the extreme exposure ranges. Thus, they exist but are reserved for emergency use only.

Even tables published for routine use may be seldom employed and must be periodically reexamined. The Navy has an elaborate system for reporting all diving operations to the Naval Safety Center and studying the outcome of decompressions conducted. Berghage, et al. examined diving operations conducted over a typical two-year period.(6) They emphasized that the greatest amount of data and safest tables were concentrated in shallow diving. Overall 8604 divers over a two year period required decompression and resulted in a decompression sickness incidence of 0.41% (35 cases). However the distribution of decompression sickness was not uniformly or proportionately distributed among the categories of recorded dives. Deeper and longer dives accounted for a disproportionate number of cases. Specifically, dives to 100-200 fswg accounted for only 12% of the dives but 57% of the decompression sickness. Saturation dives accounted for only 0.3% of the dives but 20% of the decompression sickness. Clearly, the tables in these areas carry somewhat greater risks than the shallower and shorter tables.

Historically, those proposing new diving tables throughout the diving community have seldom been able to test them to a high degree of reliability. Testing is conducted to practical limits of time, money and resources. The tables are released for use in some form of operational manual with only minimal reference to their development, testing and reliability. Accumulation of diving experience follows but accumulation

of this data is not synonymous with improving the tables. It is frequently necessary to continue using the available tables until resources are available to design and test new tables. In March 1981 the U.S. Navy conducted salvage operations of an aircraft in 230 feet of water and utilized standard U.S. Navy helium-Oxygen tables that had received very limited operational use up to that time. Careful support with extra master divers, extra chambers and experienced Diving Medical officers was provided...and the care proved justified. Thirty-eight divers were decompressed on standard Helium Oxygen tables after dives to 230 feet. Six of these suffered decompression sickness which resolved with prompt treatment. The Navy is developing data to improve these deeper Air and Helium-Oxygen tables. In the meantime though, the existing tables are the best we have available and must be utilized with appropriate support if the need arises.

Divers are made aware during their training that there is a finite probability of decompression sickness with each dive requiring decompression and this risk increases as the depth and time of exposure increases. While establishing an arbitrary limit of decompression sickness incidence of less than 2% for all diving operations (as required in the Institute of Civil Engineers for work at the Tyne Pedestrian Tunnel in England)(7) is laudable, it appears an unrealistic goal for deeper, longer diving operations at present. Far more data must become available and new tables explored, both experimentally and operationally, for decompression tables to achieve such an objective.

During the 1970's NSMRL continued to gain knowledge concerning the characteristics of inert gases and the vagaries of successful decompression from shallow saturation dives. Initial laboratory studies involved few subject for any given exposure profile. Larson and Mazzone(8) explored decompression procedures for excursions from a submerged habitat. They exposed from 3 to 8 dogs on six different excursion profiles before proceeding to human exposures where from 1 to 6 humans dove the same profiles. Markham(9) exposed 13 subjects at 40 feet in cooperation with the Tektite project to show that the mathematical assumptions used in computation of Nitrogen decompression tables would have to be more conservative. The number of subjects was small for statistical validation in each case. Useful tables and information were evolving. Operations during projects Tektite and Flare as well as research at other facilities slowly added to the data available.

NSMRL continued the exploration of saturation diving and decompression with air and Nitrogen-Oxygen mixes in the early 1970's.[10] Projects SHAD and NISAT (Tables 3 and 4) relied in part on information carefully gathered at the University of Pennsylvania in the International Decompression Data Bank. Drs. Kenyon and Hamilton at Ocean Systems, Inc., Tarrytown, using information from the NOAA OPS effort, computed the initial experimental tables for these efforts. In spite of the care that went into these calculations the first human exposure succeeded in bending two divers out of two. Further modifications gave the laboratory useful tables. Three years later the laboratory was computing its own tables using the same mathematical model but had only 18 saturation decompressions on which to judge the safety of the tables so generated with minimal testing. They were the best tables available to the Navy, had the Deep Submergence Rescue Vehicle been called on to effect a pressurized rescue utilizing Air or Nitrogen-Oxygen saturation decompression techniques.

TABLE VALIDATION

DIVE	NO. SUBJs
AIRSAT-4	18
AIRSAT-5	33
AIRSAT-6 (in progress)	6

Rates based on K(Pi02) Model (Vann)

Table 2. Number of dives conducted for initial table validation at NSMRL during AIRSAT 4-6 dive series.

TABLE VALIDATION

DIVE	NO. SUBJs
Pre-SHAD	2
SHAD-1	2
SHAD-2	2
SHAD-3	3

Table 3. Number of dives conducted for initial table validation at NSMRL during SHAD dive series.

NSMRL would be very happy to have the rescue tables we are producing ultimately show an incidence of less than 2% decompression sickness. As an example of the problems we face, Figure 1 shows a graphic projection of data and theories we examined to estimate the magnitude of the initial decrease in pressure that a submariner might be able to tolerate when transferred from a mother submarine following saturation exposure to

compressed air up to 132 fswg in a disabled submarine. It is overlayed with unpublished data from current laboratory experiments which address this area of investigation. Figures 2 and 3 represent the dive profiles developed from the theoretical and historical data contained in Figure 1. Table (2) shows the number of man dives conducted to date to test the hypothesis that an initial excursion could be made to depths predicted by the type of data shown in Figure 1. It has taken many dives and dollars to establish the validity of our predictions... and useful emergency guidelines. The numbers are not sufficient for a high degree of confidence as yet, even with a good deal of preliminary diving and 10 clean man dives at the extremes of the table. A draft of a manual of tables and procedures is currently in preparation by NSMRL and Submarine Development Group One and will be submitted for review and approval for potential emergency use in Deep Submergence Rescue Vessel (DSRV) operation.

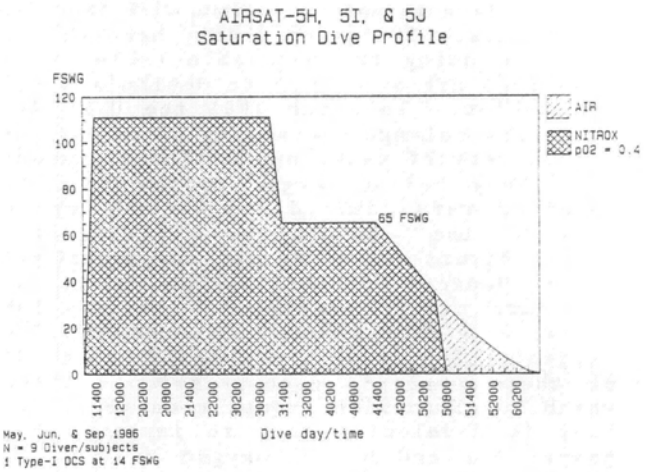

Figure 2. Profile of AIRSAT 5 H-J at NSMRL.

TABLE VALIDATION

DIVE	NO. SUBJs
NISAT-1	3
NISAT-2 *	3
NISAT-3 #	3

* USN HeO2 Table
\# USN HeO2 Table (modified)

Table 4. Number of dives conducted for initial table validation at NSMRL during NISAT dive series.

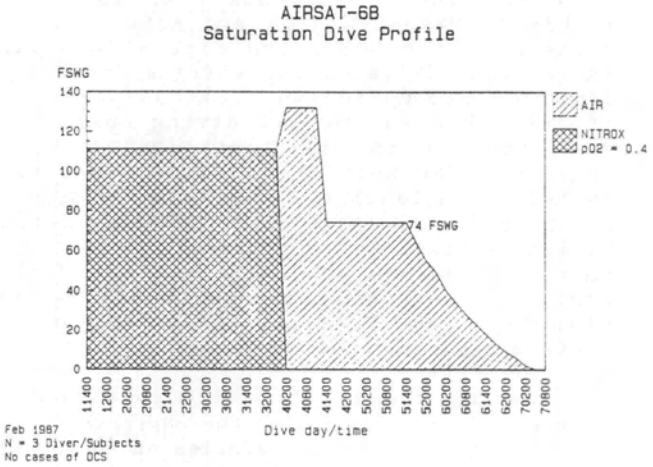

Figure 3. Profile of AIRSAT 6 A-B at NSMRL.

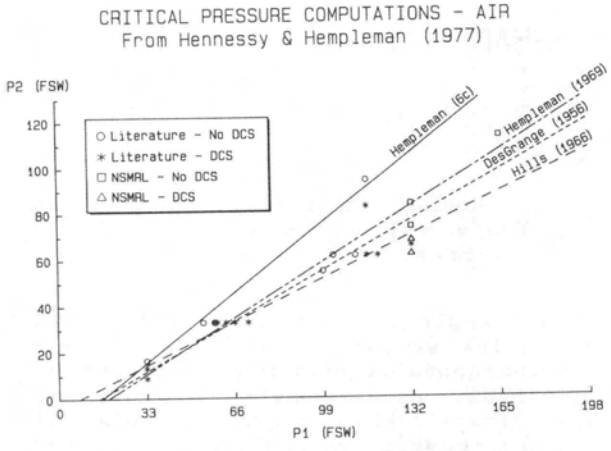

Figure 1. Critical pressure computations-Air. From: Hennessey and Hempleman, 1977. Overlayed with NSMRL data.

Recently investigators at NSMRL felt that a mathematical procedure for computing decompression rates proposed by Dr. Vann of Duke University offered simplicity and reliability.[11] Therefore they have adopted the model for computing ascent rates from Nitrogen Saturation dives and continue to test this model in current, carefully controlled, laboratory situations.

Dr. Thalmann at the Experimental Diving Unit suggested in 1984 a decompression table for ascent from saturation on air at 60 feet which had 10 clean man dives. Preliminary work consisted of 7 other exploratory dives involving 71 divers.[12] This profile with its large number of man dive data points offers better statistical validity than other comparable profiles. It could currently be utilized in submarine rescue with shallow air exposures if the need arose.

Validation of decompression tables must be based on historical perspective for initial calculations, laboratory testing, controlled field trials under operational conditions, long term evaluation by end users with appropriate modifications by the promulgating authority and adequate validation utilizing statistical methods as appropriate.

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ADDITIONAL COMMENTS BY CAPT HARVEY

Someone asked about end points at NSMRL. We use decompression sickness, Type 1 or Type 2, as an end point, but we do not consider skin bends as an end point. We do take doppler readings on all of our dives. We do not change our profiles based on those doppler readings. We feed the information back to DCIEM, with whom we have an exchange program. DCIEM is, I think, taking the lead in the doppler work.

The next thing I would like to say is that most of our tables are being developed for submarine rescue. They are developed for an 18 to 45 year old age group which is the primary group that you see on submarines. By the time a man gets to be in his 50's, he is usually off of submarines or he has become so senior that he is in staff jobs. It is an all male population. We use divers who can pass the United States Navy Diving Physical, which is pretty well laid out and I will not dwell on it. But we are aimed at a specific healthy group of people for a specific mission. We are currently aiming at dry diving decompression techniques in our current work.

One other point. In the series of dives we are in right now we are trying to pick the maximum jump that we can make from 132 fsw. So far, we have six dives; to pick the area we can jump to, 33 dives. That is not a lot of numbers. It is a lot of saturation diving, but it is not a lot of numbers.

DISCUSSION FOLLOWING CAPT HARVEY

CHAIRMAN SCHREINER: The Supervisor of Diving, apparently, is the ultimate authority that accepts a decompression profile that has been recommended to him; correct?

CAPT HARVEY: Actually, the Naval Sea Systems Command, I think, is the one that actually publishes the Diving Manual which is promulgated, but the Supervisor of Diving certainly is the one who makes a recommendation to do it.

CAPT GARRAHAN: The chain of events in validating the decompression tables is as CAPT Harvey has indicated. There are two other checks and balances. We use NMRI also to review and comment on any tables that come out of or pass through NEDU. Once we get the comments from NMRI, NEDU, or any other activity that we may request, we then forward the package to the Navy Medical Command, MEDCOM 21, who is CAPT Bumgarner, who then makes a final review and comment. The tables then come back to us and we, in-house, then do an independent "eye search" of all of the tables to be sure they are the proper format and so forth.

Once that is done, we then publish them in the U.S. Navy Diving Manual. We are in the process at this time of rewriting Volume 2, Mixed Gas Diving. We expect that volume to be ready for issue about August of this year. Volume 1 is also in a rewrite phase at this time. We expect that volume to be out about February of next year. Naval Sea Systems Command is the final authority. Admiral Reardon does sign on the dotted line, but my office is accountable for maintaining the Diving Manual.

CHAIRMAN SCHREINER: So there is a methodical chain of review.

CAPT HARVEY: And a good review process, too.

DR. KINDWALL: Claude, you mentioned Berghage, et al., the work that was done in validating and looking at where the bends incidence was (ref 6). They showed that there was a disproportionate amount of DCS for the longer deeper dives as opposed to the shallower dives. There is been a problem, at least in my experience, with that method of doing it (using the records from the Navy Safety Center) where the Navy typically does not use their own tables.

In other words, if you are using the 150/30 table the dive has not been made anywhere near 150 feet for 30 minutes. All the dives on that decompression schedule are made at 140 feet or less. Every time, the diver jumps a table or a time or a depth.

Case in point: we had six divers who had been on the Skylark, all on the 150 for 30 table. We called up the Experimental Diving Unit and said, "Do you have any problem with the 150 for

30 table? We have got them all, six in one day. Filled every chamber in town."

Well, they came back, "No. That table is perfectly all right. There is nothing wrong with it."

Those particular six divers all went to exactly 150 feet for exactly 30 minutes. All decompressed exactly on the money, where no one ever does that, normally. Is there any method for extracting data from the records where you could take the actual dive made, the actual depth and compute the end values of all of the tissues at that time to see how close you were to real limits.

CAPT HARVEY: Our tables allow and our recording system records the actual depth of the dive and records the table used.

CAPT HARVEY: It is possible--as long as people are *honest* in filling them out, but I think there is sometimes a question about that--whenever you get huge numbers of papers filled out by huge numbers of people, I always question how accurately everybody is in doing it. But, if we are willing to accept the recorded values, you can look at the actual depth and actual time of the dive, as compared to the table that was used.

Now, the problem is, as you point out, we may slide a depth and slide a table to allow for hard work in very cold water. The Navy's approach to these variables is to simply slide times and tables in order to make up for the extra stress involved. So that if you are going to selectively start analyzing this data for whatever mathematical model you want to compare it to (I grew up with the half-time tissues and am comfortable with that) you can go back and get useable data out of there as long as you accept the validity. So, if you are really going to test tables in the 10 by 10 block we were talking about, you are going to have to do it in a laboratory or you are going to have to get a recording transducer.

DR. KINDWALL: So, really, what we are saying, then, is those data that were recorded by Berghage are not relevant. I asked a Navy master diver who was in for 26 years, "Did you ever decompress anyone on the appropriate table?" And he said, "No."

CAPT HARVEY: We tend to vary or "slide" tables, but I think your example is perhaps a bit extreme. I have been out on an awful lot of at-sea dives, and we *do* use the tables.

For instance, the 230 foot information I mentioned on the salvage of the airplane out in the Pacific, we were in a magnificent situation there. We had to move the boat after every dive. The divers were rested. The visibility was excellent. It happened that we were diving within the 10 foot frame of the tables, but we dove every table right to the money, and bent 3 out of 17 on the first tables we used.

Well, we were able to do it because we were in a very controlled situation. So, there are, indeed, a lot of tables in there that are controlled. But I certainly would think that in developing new tables and other things you can get some clues, some statistical implications, from those tables.

DR. LAMBERTSEN: In addition to the numbers that you suggested extracting, you would have to have awareness of what the other conditions of the diving were. Without those, which are the reason for the sliding, the kept computations would have no meaning.

CAPT HARVEY: Those are somewhat covered in our recording system. We list bottom conditions. We list water temperatures. We list other variables that at the time the form was designed seemed to be pertinent for future evaluation of just what we are talking about. It takes a lot of work to do it.

DEVELOPMENT AND VALIDATION CONSIDERATIONS IN DECOMPRESSION TABLE DEVELOPMENT

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Introduction

In April of 1985 the Canadian Armed Forces accepted into service a set of new Air Decompression Tables based on the DCIEM 1983 Decompression Model. In this presentation, it is intended to describe the major factors that influenced the development and validation of that model. This presentation will be a cross between what was planned to occur and what evolved over the course of the project. As such, this may perhaps be considered a guidebook on this topic based on DCIEM's experiences in this area.

Development

In the development phase of the 1983 model the following elements were present though not all in the sequence shown. Certainly not all of them were as clearly defined as they are shown here:

A) Identify team
The group that is going to progress this development must include representation from the Scientific, Medical and most importantly from the Operational sector. Ideally this team should also be under the direction of one of the Operational members as ultimately it is the Operators that must live with the resulting tables.

B) Define approach
This entails defining what the objectives of the program are to be and more importantly deciding which method is going to be used to achieve those objectives. Two alternatives are:

i. Scientific - the exact limits of the model chosen are determined through calculation and experimentation and then the limits are set for the Operators.

ii. Operational - the limits that the Operators require are defined and then the chosen model is evaluated out to those limits only.

Traditionally the Scientific approach has been the favored method but this is very time-consuming and expensive. Also for the results to be valid you must be prepared to hurt people in the name of science. This generally is frowned upon by Ethics Committees and subjects. The Operational approach is obviously faster and less costly but it is not good science and it may be hard for the scientific and medical members of the team to adopt this method. DCIEM having limited funds, a small staff and a pressing operational need chose this second option and at this point in the development set out the following limits:

i. Air Diving Normal Limit - 180 fsw (54 Msw) for 30 minutes;
ii. Exceptional Exposure Limit - 240 fsw (72 Msw) for 40 minutes;
iii. Repetitive Dive Limits - 180fsw/30 + 180fsw/30 with a 2 hour surface interval;
iv. Use of In-Water Oxygen and Surface Decompression Techniques in addition to Standard Air Decompression.

C) Identify or develop a candidate model
Decompression research at DCIEM was started in 1962 by Kidd and Stubbs who set out to develop an instrument which would monitor a diver's depth/time history and provide instantaneous decompression information. By 1967, they had developed a successful decompression computer based on about 5000 man-dives. After further analysis, Stubbs modified the model again in 1970 to improve the safety in the 200 - 300 fsw range. This final model became known as the Kidd-Stubbs (KS) 1971 model and this became the starting point for the DCIEM 83 model.

D) Computer modelling
A series of representative profiles should now be calculated using the mathematics underlying the chosen model and then the results analysed against the results for the same profiles calculated using other accepted decompression models (R.N., U.S.N.). At this point the parameters in the model can be adjusted, if necessary and a trial and error senario can be quite useful.

E) Physical modelling
Once the model appears to be functioning acceptably with digital simulation it is necessary to confirm that the model works in real time with a pressure input. At this point, it is

necessary to hook the computer up to a test chamber and to run the same profiles unmanned to confirm that link and to start the process of building up subject confidence in the model.

F) Procedure definition
With the model and the computer hardware ready to go it now remains to relate the mathematics to the real world and to define the procedures that the divers and chamber operating personnel will utilize during all of the dives. Again here is an important area in which the concerns of the Operators should be the primary determining factor and due consideration given to the following areas:

i. Standardization of rates and procedures
ii. Supervisor flexibility
iii. Above all K.I.S.S.

Validation

At this point, having decided upon the objectives and the approach, having identified and verified a model, and having decided upon the procedures to be used it is now time to start into the lengthy process of validating the model. The following factors should be considered in this regard:

A) Selection of profiles for testing
This can be quite difficult due to the requirement to balance the number of different profiles against the different decompression methods so that a comparative evaluation of the different methods can be conducted. In addition the profiles chosen must cover the following areas:

i. The Normal Limiting Line
ii. The Exceptional Exposure Limiting Line
iii. Any areas where the amount of decompression has been reduced from that given under other accepted methods
iv. Known problem areas of other methods (ie USN 150fsw)
v. Spot checks over the range of the model

B) Number of dives
Another difficult area that if left to pure statistical analysis would make any validation run into a time frame of decades. In the case of the DCIEM 83 model we attempted to achieve 50 solid data points per aspect of the model investigated and in total we achieved about 800 man-dives on the model itself. Aided by the data available from the work of Kidd-Stubbs (5000 man-dives) and the fact that we were more conservative than the USN and RN models we felt that this was more than enough. Some of the aspects to consider here are:

i. How many dives are required per profile selected?
ii. How many dives are required per decompression method?
iii. How much time is available?
iv. How many dive subjects can you handle per chamber run?
v. How many dive subjects do you have available?

Generally it is the last three factors that tend to be the driving force in a program of this nature.

C) Data collection and analysis
Traditionally the prime indicator of success in this type of validation has been the number of bends/number of dives conducted. This type of analysis is extremely subjective, it is affected by a large number of known and as yet unknown factors and by itself provides very little information about the effectiveness of the model. For that reason DCIEM decided to utilize the technique of Doppler monitoring of the dive subjects. Though Doppler as an absolute indicator of the stress of a particular profile has limited value it does give an indication that something is going on. It therefore can be used very effectively to give a comparison of stress between different profiles, different decompression methods and different dive subjects. Some of the other factors that must be considered in this section include:

i. How do you assess the results of a dive, a series of dives or the whole mass of data?
ii. What do you count as good dive data?
iii. What data can you disregard as being worthless?
iv. What weighting factor do you give to predisposing factors when assessing bend data?

D) Subject selection
The subjects selected should reflect the age, weight and height range of your subject population. There should also be a sufficient number of subjects available to prevent acclimatization. You want to get enough dives per subject, though, to make your training requirement manageable and also to allow the inter-profile, inter-method

comparisons that are vital to the validation process. Some of the factors that enter into here include:

i. Physical Fitness - all subjects must be fit to dive and subjects that have obvious predisposing factors, like obesity, should be ruled out.

ii. Trained vs Untrained Subjects - Though you do give up some of the scope of your subject population by using trained divers, you can dramatically reduce the predive training you must give the subjects and you reduce the effects that apprehension and narcosis may have on your results.

iii. Legality - This is a very large question in today's climate. Our investigation into this area led to the ruling for DCIEM that it is quite legal to use civilian subjects in our chambers but they still have the right to sue and they will win if they can prove negligence. On the question of waivers to participate, the current opinion is that they carry no weight legally but that they still have a useful value as a psychological dissuader.

E) Subject control

This is the area that undoubtably will give you the majority of your problems. Identifying and acquiring the subjects is easy compared to the problems that are associated with trying to manage a group of 20 dive subjects who have little or no comprehension of the requirements of the validation process. The factors that must be taken into account in this area include:

i. Medical Approval - All subjects must have completed a diving medical and their records must be vetted by your team's Medical member prior to allowing the subject to dive.

ii. Briefing - All of the subjects should receive a comprehensive briefing on the project covering the background and development of the model and the results achieved todate. On completion of this and a suitable question period each subject should be required to sign a consent form that clearly states that the individual is a willing volunteer and that they are well aware of the risks involved in participating. It is then recommended that a further briefing on administrative details should follow and then the subjects be broken up into their dive teams and introduced to the staff member who will be their team leader over the course of the dive series. From that point on each team leader has the control and responsibility for their team.

iii. Exercise Restrictions - To reduce the chance of a masking or predisposing injury a restriction on subject exercise is required for the series. It is suggested that there be no UNUSUAL exercise for 24 hours before a dive and no exercise at all for 4 hours post Doppler monitoring.

iv. Drug and Alcohol Restrictions - Again to prevent undesirable side effects all subjects should be requested not to consume any alcohol within 12 hours of a dive and to inform the Medical staff if they take any medications within 24 hours before a dive.

v. Predive Screening - Experience has shown that subject honesty or judgement cannot always be depended upon. Therefore, a pre-dive screening by one of the medical staff of all subjects is highly recommended.

vi. Time between dives - This must again be a compromise between avoiding diver acclimatization and getting value out of a group of subjects in a set time frame. We used 36 hours as the minimum time required between dives which resulted in each subject making a maxium of 2 dives/week. Each series then ran 3 weeks consisting of 1 week training and 2 weeks diving thus giving each subject 4 dives. One furthur aspect in this regard is the necessity to ensure that the subjects are well briefed not to participate in any other type of diving

during the 36 hour period and that even a 10 ft quick dip on their day off will render them unusable for the next day's dive.

vii. Personalities - Having previously mentioned subject honesty you must now add subject unfamiliarity with bends symptoms, unwillingness to report symptoms and unreliability.

viii. Bends Watch - An effective system must be set up to quickly and correctly deal with bends incidents that may occur during the evening hours. This should include a beeper/telephone recall system and a duty crew identified for each evening. This requirement must also be accounted for in your day to day plan as a 1:00 - 4:00 A.M. treatment can use up a lot of your staff.

ix. Other concerns - Attention must be given to the fact that you are requiring a lot of the individuals' time on a daily basis and though it doesn't amount to much, things like subject meals, entertainment and pay add to the administrative burden and can become real problems when a frozen subject who has been wearing a rectal probe for the past two hours discovers that someone has just stolen his box lunch.

F) Chamber Considerations

Now that the other areas have been dealt with and you are ready to do some diving you come up against the problems that diving in a chamber can add to your program. These include:

i. Computer Controlled Decompression - If at all possible all dives should be decompressed according to a real time computer that can monitor the profile. This way the computer takes into account the vagarities of chamber diving (ear holds, variations travel rates, etc). This also allows a much more effective comparison to be made with the unmanned runs completed during the development phase.

ii. Profile Control - In order for the data on each run to have maximum value the profile must be controlled in a manner contrary to everything dive supervisors have been taught and all the breaks must go against the subjects to achieve the worst case senario. This includes the following:

a) Going to the exact depth and staying the exact Bottom Time that the profile calls for;
b) Making any gas switches instantaneously on arrival at the stop for the computer and then switching and flushing the diver's umbilical; and
c) Utilizing the full surface interval when doing a Surface Decompression dive.

iii. BIBS Masks - Use of dry subjects or surface decompression techniques necessitates the use of these masks. This can lead to two problems; mask leakage due to poor fit and overtaxing of the chamber BIBS gas delivery system if all the BIBS masks are in use simultaneously. To combat these problems, DCIEM matched mask sizes to subjects during training and incorperated a 20% mask leakage rate into the decompression calculation. We also limited the number of subjects/chamber.

iv. Field Condition Approximation - An approximation of actual field conditions should be attempted during the validation. This should include:

a) Wet Pot Water Temperature
b) Wet Subject Equipment - This should cover the range available to your diving community (i.e. SL17, Aga, Hookah, Wet, Dry, and Hot Water suits)
c) Subject Work Levels - This should cover the range from Dry Resting to Wet Working and if possible should include work projects, swimming and the old favorite, ergometer runs.

v. Diver Safety - As dictated by the portion of the model being validated any or all of the following diver safety monitoring equipment should be used:

a) Heartrate Monitor
b) Thermal Monitor
c) Workrate Control System
d) Video Cameras
e) Communications Recorders

G) Emergency Procedures

Over and above the established Emergency Procedures that deal with chamber equipment problems it is necessary to develop procedures to deal with the kinds of problems that can arise with the portion of model being validated in each series. These include:

i. Late arrival on the bottom,
ii. Premature leaving bottom,
iii. Computer Failure
iv. Loss of Diver's air
v. Loss of Diver's O_2
vi. Loss of Chamber O_2
vii. O2 Symptom/Hit In-Water
viii. O2 Symptom/Hit In Chamber
ix. Wet Diver Core Temperature Drop
x. Failure to make Repetitive Depth

Summary

In summary, it can been seen that the whole process of Development and Validation of a Decompression model is a project not to be entered into lightly. I think as well that the approach taken by DCIEM in this development is flexible and can be easily adapted to virtually any application in this field. In closing then I would like to say that if you think that this looks complicated and involved, I'll come back next time and tell you about the problems involved in writing the procedures for and introducing the tables to the Sailors in the Fleet.

DISCUSSION FOLLOWING CDR HOBSON

DR. ELLIOTT: You are talking about chamber evaluation of tables; we do know from past experience--certainly from the dry days, but even after wet chamber validation--that the operational evaluation before you release it to the Fleet proves that the table that was thought to be okay is not. Do you have a formal program for at-sea testing of new tables, or do you just keep your fingers crossed?

LCDR HOBSON: No. The Canadians are much less formalized for the introduction of tables into the service units because there is only a total of 125 clearance divers in the Canadian Forces, and 35 officers. Basically we send the information on the tables and the validation out to the coasts and to *Cormorant*. We attempted to run a short optimal evaluation on the coast, but it did not meet with a lot of success because we put too many things into the evaluation time period. It was during the time that HMCS *Cormorant* went down to NEDU. The NEDU divers came on board with 47 pieces of equipment to try, and *Cormorant*'s diving officer decided, "We do not want to start using new tables here in case everyone falls down and the Americans think badly of us." So, they did not.

Throughout the development, however, we provided the Canadian Underwater Training Center with decompression computers and they were running dives on them. Pembina Exploration Company in Lake Erie also took our preliminary tables and started doing dives with them. We did an introductory training program for the Fleet that involved some diving, again of a limited nature. I think in this case we did not opt for a full-blown field evaluation because we were so far inside (more conservative) what the rest of the world was already using and swearing did not need to be changed.

MR. HOLLAND: What about exercise restrictions? One of the things that I believe may be critical in this sort of thing is people who are weight lifters and that sort of thing--did you put a limitation on those types of people because they, by nature, are always sort of pushing themselves to the limit and can cause problems before you dive them and then would subsequently show up with DCS.

LCDR HOBSON: Yes, we did. Again, with the exercise restriction, we initially set out that no unusual weight lifting training was to be done. One of the worst cases of decompression sickness in the Canadian Force was in a young fellow who was not this series. He was at DCIEM during the Kidd-Stubbs work--he was very proud of himself and of his chiseled physique. He wanted to show that morning that he could double his weight. He went in and he pushed everything. And then he went on a very hard long dive. And God knows how many 6 A's and weeks in hospital he spent later.

On the current series on the helium tables, we have somewhat of an increase on the restriction; here we do not allow weight lifting 24 hours before.

MR. HOLLAND: Drugs and alcohol? You know, whether we like it or not, we do have those who are partial to a little drop of the wacky-packy, and sometimes something stronger. I do not know if that really would have any effect on the decompression, ultimately. But were you doing random testing on that in any respect at all, or do you just tell them that they could not do it, and believe that you do not have that problem?

LCDR HOBSON: No. What we did not say is, "All right, everybody, here is your bottle. We are going to test you," and all that sort of thing. We said, "Hey, if you are doing drugs, tell us so that if something happens we can say, "Well, maybe it does have an effect." I suppose the most serious thing we had reported was codeine capsules or something like that. They will tell you what they want to tell you.

But after the fact, where we had some serious hits, there was one individual who ended up in hospital in Type 2 because he delayed. He went to a party. He got drunk. Got blown away, and ended up in the hospital with three or four 6 A's. They did a full neurological and after-effects scan on him, but there was not any indication of drugs being involved in that particular instance.

DR. BENNETT: I would like some more information about the computer itself, how you had it connected to the chamber. When I was at DCIEM they had eight of the computers around, and they went by the one that was holding back the greatest amount. I was quite concerned about this because you already have a terrific randomization with eight computers, and you are only picking out the one that is giving you the hot line. Do you just use the one computer?

LCDR HOBSON: We have one computer, and a backup in case it falls over.

DR. BENNETT: But you run on the one computer giving you advice, not a battery of them.

MR. NISHI: It is a digital computer, a microcomputer.

DR. HAMILTON: They give the same answer, unlike the earlier pneumatic models.

LCDR HOBSON: They do. I never mentioned that one. But digital instruments drive you nuts. We have digital depth gauges, and also the manual panel, and then the computer that gives a digital readout. We had to establish that the computer depth was the master depth. Whatever the computer said, that is what we went with.

[EDITOR'S NOTE: Use an optical pickup which produces a digital signal on your master Bourdon tube gauge and then you will know exactly where you are and everybody will be happy.]

USN EXPERIENCE IN DECOMPRESSION TABLE VALIDATION

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INTRODUCTION

The US Navy has been active in developing and validating decompression procedures for over 50 years. A majority of this work has been done at the Navy Experimental Diving Unit (NEDU), which was initially located at the Navy Yard in Washington DC and moved to Panama City, FL in 1974. Most of these dives have been documented in NEDU Reports and Tables 1 and 2 are a summarization of the published data with references. These efforts have encompassed over 12,000 man dives resulting in approximately 550 cases of decompression sickness. It should be noted that Tables 1 and 2 do not represent a complete compilation of the total US Navy effort since it includes neither dives done at other US Navy facilities, nor the many dives done at NEDU which were never documented in NEDU reports. Rather, these tables should be considered as a lower limit estimate of the US Navy's efforts in decompression table validation.

This paper is divided into three main sections. In HISTORICAL OVERVIEW efforts through 1970 will be described which resulted in development of most of the USN decompression procedures currently in use. In RECENT STUDIES efforts from 1970 through the present will be discussed, all of which I have either been personally involved in or have personal knowledge of. In CURRENT CONSIDERATIONS IN TABLE VALIDATIONS will be presented the considerations which should be taken into account for decompression table validation as well as the basis for these considerations. It should be noted that the opinions expressed in this paper are my own and not necessarily US Navy policy unless explicity stated as such.

HISTORICAL OVERVIEW

The USN simultaneously developed Air and Helium-Oxygen bounce dive procedures using similar methodology. Since these developments were concurrent there were some methodological changes made in one effort based on the results of the other. Since the USN Standard Air Tables are the most widely used of USN Tables their development will be of most interest. Of secondary interest will be the Helium-Oxygen decompression tables. Other efforts are described for completeness.

Standard Air Tables

The USN inherited their Air Decompression Tables from the Royal Navy in the form of the Haldane Tables. These tables formed the basis for the Bureau of Construction and Repair (C&R) tables which were replaced in 1937 by a set of USN developed tables (called the USN Tables in Table 1) which underwent a single revision in 1957 (11,12) (called the Current Tables in Table 1). Much of the validation done leading up to development of the USN Tables was involved in determining the air no-decompression curve and investigating theoretical tissue nitrogen offgassing rates (1). In one early study it was conclusively shown the post-dive exercise increased the probability of decompression sickness (DCS), rather than decreasing it because of increased blood flow as had been theorized (4). Based on an analysis of previous experience, Dwyer (9, 10) systemized the calculation of decompression tables and programmed a UNIVAC computer to produce a set of schedules which were validated over the period from 1956-1957. In the end, however, empirical modifications were made to some schedules in order to reduce the incidence of DCS. Thus, the Current Standard Air Tables cannot all be calculated directly from the mathematical model initially used to program the UNIVAC.

In validation of the Current Standard Air Tables, it was initially planned by Des Granges (11) to dive each of the 88 computed air schedules a total of 6 times. When testing repetitive dive tables, 61 different representative combinations were chosen and dove twice (12). On the bounce dives, once 6 DCS free dives were obtained on a particular schedule it was not dove again. Exercise was performed at depth by lifting a 70 lb weight 26-30" ten times each minute while divers rested during decompression. Water temperature was set to a comfortable level (11). As a result of Des Granges' testing the maximum air depth was set to 190 FSW, and the resultant air decompression tables are those currently in use today.

Air Surface Decompression Tables

The concept of surface decompression was demonstrated to be practical by Hawkins and Shilling in 1935 using the old C & R Tables (3). The obvious advantages of this procedure caused vigorous development from 1942-45 with operational dives done by Gouze and chamber dives being conducted by Van Der Aue (3). In the latter study the effects of exercise, immersion and temperature were investigated. Exercise was done by weight lifting at depth (as described above), and divers rested during decompression. It was clearly demonstrated that exercise at depth increased the incidence of DCS and since that time exercise at depth has been used in all USN bounce dive validations. Immersion was observed to have a DCS incidence similar to dry dives so long as divers exercised at depth. No effect of water temperature on DCS incidence was reported although it varied from 38-64^{o}F. Van Der Aue did stress the relationship between post dive fatigue and inadequate decompression. Van Der Aue's surface decompression studies were done using the 1937 USN Air Tables. After the air tables were

TABLE 1

NEDU Nitrogen Validation Dives

AIR AND N2O2 BOUNCE

DATE	MAN EXPOSURES	DCS	TABLES	REFS
1933–35	2143	46	AIR NO–DECOMPRESSION	(1)
1949	201	18(33)	AIR NO–DECOMPRESSION (POST DIVE EXERCISE)	(4)
1956–57	564	27	AIR BOUNCE DECOMPRESSION	(11)
1956–57	122	3	AIR REPETITIVE DIVES	(12)
1960	174	6	AIR N2O2 EQUIVALENT AIR DEPTH	(19)
1977–80	683	35	0.7ATA CONST. PO2 IN N2 BOUNCE, MULTI–LEVEL REPETS	(33,34)
1984	837	45	REVISED AIR/0.7ATA CONST. PO2 IN N2 BOUNCE, MULIT–LEVEL REPETS	(36)

AIR AND N2O2 SURFACE DECOMPRESSION & SATURATION

DATE	MAN EXPOSURES	DCS	TABLES	REFS
1935	406	?	SUR–D AIR(C & R TABLES)	(8)
1942–43	130	0	SUR–D AIR(USN TABLES)	(8)
1945	282	27(25)	SUR–D AIR(USN TABLES)	(3)
1951	1576	19(118)	SUR–D O2(CURRENT TABLES)	(8)
1957	76	4(9)	SUR–D AIR(CURRENT TABLES)	(13)
1957	46	>13	AIR SUBSATURATION	(14)
1961	259	>100	N2O2/AIR (ALTITUDE PROVOCATION)	(20)
1979–86	111	11	60 FSW AIR SATURATION (TREATMENT TABLE 7)	(38)

NUMBERS IN ( ) ARE REPORTED MILD DCS,UNTREATED

TABLE 2

NEDU Helium Validation Dives

HELIUM OXYGEN BOUNCE

DATE	MAN EXPOSURES	DCS	TABLES	REFS
1939	700	?	HeO2 PARTIAL PRESSURE	(2)
1949	424	6	HeO2 PARTIAL PRESSURE (INCLUDES SOME OPEN SEA)	(5)
1950	49	12	DEEP HeO2 PARTIAL PRESSURE	(7)
1959	254	19(38)	HeO2 SEMI-CLOSED SCUBA	(16,17)
1965	486	6(27)	HeO2 SEMI-CLOSED SCUBA	(21)
1970	74	18	REVISED HeO2 PARTIAL PRESSURE	(29)
1984	1582	57	0.7ATA PO2 IN He CLOSED CIRCUIT SCUBA	(35)

HELIUM OXYGEN SUB-SATURATION AND SATURATION

DATE	MAN EXPOSURES	DCS	TABLES	REFS
1965-68	356	45	ADS IV,SEALAB III SUB-SAT	(24,30)
1966-68	97	8	SEALAB III SAT DECOMPRESSION	(28)
1969-70	74{1126}	13	SAT REPETITIVE EXCURSIONS	(23,25,26,27)
1974-76	72{245}	5	UNLIMITED DURATION EXCURSIONS	(31)
1978-87	42{78}	10	REVISED SAT DECOMPRESSION AND UNLIMITED DURATION EXCURSIONS	(32,46)

NUMBERS IN ( ) ARE REPORTED MILD DCS, UNTREATED
NUMBERS IN { } ARE TOTAL MAN EXCURSIONS

revised in 1957, Workman performed dives to establish surface decompression procedures using these revised air tables (13). The main concern with the revised air tables was the increase in ascent rate from 25 FSW/min to 60 FSW/min.

Oxygen had been known for some time to decrease the incidence of DCS if breathed during decompression and in 1951, Van Der Aue et al (8) tested surface decompression procedures breathing oxygen. This was a large dive series with 1316 dives done in the chamber and 252 done at sea. Eight additional dives were done on selected divers who had experienced DCS. Exercise at depth was either by lifting a weight or by walking on the bottom. Some 212 man dives were done in warm sea water (67-76°F) off of Key West, Florida and 151 were done in cold water (38-51°F) in a chamber. Based on the experience of 3 divers who made a total of 8 dives in both cold and warm water it was concluded that the incidence of DCS in cold water was lower than in warm, an observation still much debated. The Surface Decompression Tables using Oxygen resulting from this dive series are the ones currently in use. Since they were computed independently from the air tables in use at the time, they were not revised when the air tables were revised in 1957, and are still in use.

Other Air and N_2O_2 Tables

With the advent of mixed gas SCUBA and the desire to minimise decompression by using increased inspired oxygen levels a series of dives was done in 1960 to test the Equivalent Air Depth Theory (19). In a subsequent dive series to test this theory divers were taken to an altitude of 18000 ft 30 min after surfacing from a dive (18,20) to see how long it took to provoke pain-only symptoms of DCS (Table 3). Dives were graded as more stressful the shorter the time to symptom development at altitude. The technique of Altitude Provocation was not used in any other dive series most likely because of the complexity at having to man an altitude chamber as well as a hyperbaric chamber. The intent of the Altitude Provocation technique was to develop a more objective method of assessing the adequacy of decompression than the symptom ranking technique of Snyder and Duffner developed in 1958 (15). While the so-called "Snyder Score" (Table 4) was developed using some 176 air no-decompression and decompression dives it was only used as a method of evaluating dives during development of the HeO_2 SCUBA Tables (16, 17, 21).

In an early effort to develop some air saturation decompression tables Workman did some 140 FSW dives with bottom times from 90 to 360 min (14). These were dry, resting dives and these conditions were based on an observation by Van Der Aue that exercise made little difference in the DCS incidence for long bottom times.

Helium-Oxygen Partial Pressure Tables

Documentation of the development of these tables is not so complete as for air dives. In one of the earliest NEDU reports some 700 man dives to depths of 500 FSW are cited which formed the basis for the Helium-Oxygen Tables (2). Another large series was done by Van Der Aue in 1949 in which schedules in the 75-429 FSW depth range were dove while testing a new venturi system for the Mk V CO_2 scrubber (15). In 1950, an attempt was made to extend the depth range of the current Helium-Oxygen Tables and dives with 10 min and 20 min bottom times were done at 495 and 561 FSW (7). The DCS incidence on the 20 man dives was such that the investigators recommended not extending the depth-time limits of the tables. All of these dives were done submerged with divers exercising on the bottom.

TABLE 3

Altitude Provocation

(KIESSLING AND DUFFNER, ref 18)

SURFACE INTERVAL (MIN)	ACTION
0– 15	REST
15– 45	DEEP KNEE BENDS
45– 50	ASCENT TO 18000 FEET AT 6000 FEET/MIN (ON 100% 02 AT 10000 FEET)
50–110	DEEP KNEE BENDS AT 18000 FEET
110–115	DESCENT TO 1 ATA

TABLE 4

Modified Snyder Score

(AFTER KIESSLING AND WOOD, ref 20)

0- No Symptoms

1- Itch

2- Slight Rash or Fatigue

3- Moderate to Severe Rash or Fatigue

4- Dull Ache

5- Sharp Pain or Multiple Aches

6- Treatment Table 1

7- Treatment Table 2

8- Treatment Table 3

9- Treatment Table 4

It is interesting to note that the effects of exercise on DCS were being taken into account at the earliest stages of the Helium-Oxygen Table development. In computing these tables the bottom times were purposefully doubled because it was assumed that the divers would be working to exhaustion while at depth (2).

The current Helium-Oxygen Surface Supplied decompression tables are the most long lived of the USN tables, no modifications having been made in them since they were initially computed. In 1970, Alexander, Flynn and Summitt tested a revised set of Helium-Oxygen tables based on the analysis done by Workman (29). Workman concluded that the decompression times for the deep tables should be increased while for shallower dives it should be decreased. The tables initially tested by Alexander et al were 200 FSW for 60 min and 250 FSW for 50 min which were some 30 min and 57 min longer than the tables in use at the time. There were 18 cases of DCS on the 54 man dives which were completed and the series was stopped without any revision to the existing tables. No explanation for not continuing the series was given in the resulting report. (29). In an unpublished analysis of USN open sea dives from 1968 to 1983 it was found that a total of 4531 dives were done to depths of 200 FSW or greater. Of these, however, 4191 were for bottom times of 10 min or less and only 12 cases of DCS were reported. There were no reported cases of DCS in the 222 reported 20 min and 30 min bottom time dives. There were 118 dives reported in the 40-140 min range resulting in 20 cases of DCS. The cases of DCS were random and did not appear to be related to depth or bottom time but the number of reported dives is too small to be analysed statistically. Earlier NEDU reports mentioned that the incidence of DCS on the helium-oxygen tables was quite low but no statistical data is presented. One likely explanation for this discrepancy between the DCS incidence on earlier dives and the DCS incidence since 1968 is that the earlier divers did more diving and became acclimatized so the DCS incidence was low. After 1968 the number of deep helium-oxygen dives done by the USN was less and the divers probably were not acclimatized.

Helium-Oxygen SCUBA Tables

With the advent of the MK VI semi-closed SCUBA diving apparatus a new set of decompression tables was needed. In 1959 the no-decompression curve for helium-oxygen was determined (14) and 6 years later Workman calculated a set of decompression tables which allowed for repetitive diving (21). All of these were warm water dives (91°F) and the series was the only reported dive series to use a modified Snyder Score (Table 4) to evaluate adequacy of decompression sickness.

Helium-Oxygen Saturation Decompression

These decompression procedures were initially tested in the 1965-1970 time period. Testing included saturation decompression schedule development (28), repetitive excursion diving, (23, 25, 26, 27) and deep bounce dive schedules to be used in the event of an emergency (24, 30). The deep bounce dives were done with submerged divers exercising at depth in 68-90°F water. The saturation decompression and repetitive excursion dives were all dry chamber dives.

RECENT STUDIES

These are all studies which the author was personally involved with since 1974. This was also the time at which NEDU moved to its current location in Panama City, Fl. The new NEDU chambers, known as the Ocean Simulation Facility, included a 15' by 45' wetpot which allowed up to 10 divers to be in the water simultaneously. This capability not only expanded the number of man dives which could be done in a given time but influenced the way bounce dive validation series were done.

Unlimited Duration Saturation Excursion Dives

These were a follow on to the earlier saturation excusion dives (23, 25) and sought to define upward as well as downward excursions (31). Usually, there were 6 divers on each saturation dive during which multiple excursions were done. Saturation was assumed to be complete within 40 hours, so this was the usual period between excursions. The set of upward excursion limits originally approved (31) had to be revised because of DCS occurring after the 180 FSW upward excursion from 1000 FSW during some operational dives. This excursion distance was decreased to 165 FSW and later to 150 FSW where no DCS has occurred since (32). Exactly what flaw in the original study resulted in apparently unsafe tables being published is unknown. One factor may be that the multiple excursions on the validation dives caused subjects to become acclimatised resulting in an increased tolerance to DCS provoking excursions. Ideally one would have liked to test only a single excursion per dive, using completely fresh subjects for each excursion but the realities of economics, time, and subject availability made this impossible. Another factor may have been that 40 hours was not enough time to resaturate. Later dives at NEDU which gave rise to DCS had divers at the initial storage depth 4 to 5 days before doing the upward excursion. Since 1978, both the upward excursion limits and decompression procedures have been re-evaluated on every saturation dive done at NEDU with further revisions being made based on experience. This will most likely be an ongoing process.

Decompression Algorithm Development

The MK-15 closed circuit UBA prompted a series of validation dives to develop decompression tables for a constant 0.7 ATA oxygen partial pressure breathing gas using either nitrogen or helium as the inert gas. (33, 34, 35, 36). All dives were done with wet divers exercising at depth and resting during decompression as in almost all earlier NEDU studies. The water was kept cold enough (depending on total dive time) so that divers were all thoroughly chilled at the completion of the dive. The Nitrogen-Oxygen dives

were multiple level and repetitive dives with divers exercising during the surface interval, this being assumed to maximise decompression stress. In a later dive series switches were made between breathing air and a constant 0.7 ATA PO_2 breathing gas during multiple level dives.

The fundamental difference between these dive series and earlier dive series was that all decompressions were computed in real-time. A decompression algorithm was first developed and programmed into a computer which then constantly monitored chamber depth and updated the decompression schedule based on the exact depth-time profile. This meant that all schedules were exact, no interpolations had to be done for delays in ascent or descent. Also, as experience was gained, the computer algorithm was changed, not individual tables. Only after testing was complete was the final computer algorithm used to compute a complete set of decompression tables. Thus, not only could all tables be computed from the same model, but the algorithm could be programmed into a microprocessor for real time computation.

Having a wet chamber which allowed 10 divers to dive simultaneously greatly increased the number of man-dives which could be done in a given time. This was especially useful during the N_2-O_2 and N_2-O_2/Air dive series where some of the multiple level and repetitive dive profiles lasted up to 6 hours, allowing only a single profile per day. During the helium-oxygen dives only bounce dives were done and initially divers were diving 3 to 4 times a week. This allowed accumulation of a considerable number of man dives but the initial set of tables proved unsafe using fresh divers. It was soon realised that this diving frequency acclimatised the divers (35, 37), and the resulting tables were unsafe for unacclimatised divers. A smaller follow-up dive series was done using unacclimatised divers having at least 60 hours off between dives and, based on 3 schedules, the computer algorithm was readjusted to lengthen all schedules (35). Open sea dives to 300 FSW have been done on these tables without incident but to date the number of operational dives have been too small to establish a meaningful operational DCS incidence.

60 FSW Air Saturation Dives

These dry chamber dives were initially done to evaluate the safety of using the USN Helium-Oxygen decompression rates after saturation on air at 60 FSW. This proved unsafe so new schedules were developed and tested (38) using the computer algorithm developed during the nitrogen-oxygen dive series above. One of the eventual spinoffs from this dive series was the publication of a new Treatment Table 7 (39) which allows an unlimited treatment time at 60 FSW.

CURRENT CONSIDERATIONS IN TABLE VALIDATION

In the most recent decompression validation dives done at NEDU (33, 34, 35, 36) the experimental design has incorporated much of the experience gained during earlier trials. However, the realities of time, money, and subject availability (resources), must also be taken into account and the influences these two considerations impose are mentioned below. Each item influencing the experimental design will be discussed individually, with relevant past experience or references cited.

Decompression Schedule Calculation: In general one will have either a set of precomputed tables in hand or a computer will monitor diver depth and compute schedules in real time. In the last three sets of bounce dive validation series done at NEDU (33, 34, 35, 36) all schedules were computed in real time. This method offers many advantages over using precomputed tables, especially when descents are delayed for ear squeezes or equipment problems. Every dive is valid as long as the diver was breathing the appropriate gas at all times. Only in the case of very long, slow saturation decompressions have precomputed tables been used in recent studies.

Schedule Modification: While not absolutely necessary for table validation a systematic method of decompression schedule modification increases the efficiency of a dive series. In the latest NEDU studies, the dive series were actually a combination of development and validation. Before starting the series, a method of algorithm modification was in hand. Thus, as experience was gained, unsafe schedules could be changed to decrease the incidence of DCS and schedules which gave no DCS which may have been too conservative could be shortened. Since it was the computer algorithm which was modified, all previously tested schedules would also change so a method of determining if retesting of these schedules was also needed, as described below.

Depth/Time Domain: Tables have to be tested over the depth/time domain in which they are to be used. In the most recent of the NEDU dive series no-decompression limits were tested (where necessary) in 20 FSW increments down to the maximum operational depth. Then the maximum bottom time dives at these depths and one intermediate time were tested. This resulted in testing 44 schedules from 60 to 300 FSW in development of the constant 0.7 ATA PO_2 in Helium Tables and 26 bounce dives during the Air-N_2O_2 Decompression Tables. Repetitive dives were selected at three depths and up to three surface intervals. This resulted in 10 repetitive dive schedules. No firm policy has yet been developed for repetitive dive testing and the number of possibe combinations is enormous. At present, judgement and experience are used to construct repetitive dive schedules which are felt to be the most stressful.

Schedule Retesting: A good deal of reliance is placed on previous dives to avoid retesting schedules unnecessarily. These dives must be well documented, well controlled, and done under what would be considered sufficiently stressful conditions. For instance, in evaluating the Air-N_2O_2 Algorithm (36) no-decompression limits were only tested where they exceeded current limits because there is a mass of literature to say the current USN limits are quite safe (1, 11, 36).

When comparing decompression dives the problem of schedule retesting becomes more complicated. In the author's experience it is the Total Decompression Time (TDT) which is the most significant variable, provided the stop depth distribution does not vary too much. In an earlier dive series (33) little difference was found in DCS incidence between dives which had a deeper first stop compared to those with a shallower first stop. So, when the decompression model was modified, schedules which showed no decrease in TDT as long as the first stop depths did not vary by more than 10 FSW (occasionally 20 FSW) were not retested. In comparing newly developed tables with previously published ones the same criteria was used. The safety of published tables cannot always be taken for granted as was seen in the recent Air-N_2O_2 series (36) where some air schedules had to have TDT more than doubled compared to current USN Standard Air Schedules to avoid DCS. Thus, when one chooses previosuly published schedules for comparison, one must ensure that the exact conditions of testing are known. This includes water temperature, exercise rate, breathing gas, physical characteristics of subjects, the exact profiles tested and full documentation of all suspected symptoms of DCS. With regard to the latter, the divers should all have been examined first hand by trained diving medical personnel, second hand information is not acceptable especially in evaluating subtle or questionable symptoms.

Number of Trials: In doing manned dive trials, attaining any level of statistical significance on any one profile is unrealistic. Assuming DCS occurs randomly (40), the binomial distribution would predict a DCS rate between 0.03% and 5.45% at the 95% confidence level for 1 case of DCS in 100 man-dives. When doing validation dives a NEDU, a minimum of 30 man dives is usually planned for each schedule. If only 1 mild case of Type I DCS occurs then testing on that schedule stops. If more than 1 case of DCS occurs the schedule is usually modified. Also if the single case of DCS is a Type II symptom , especially if it is serious, consideration is given to schedule modification. No absolute rules can be given because of individual variation. In one dive series (35), 2 subjects accounted for 21% of all symptoms and one subject suffered Type I symptoms on every dive. Clearly, DCS occurring in these individuals was considered differently (but not discounted) from that occurring in other individuals in deciding whether a particular schedule was unacceptable.

It is realised that 30 dives with only 1 case of DCS on a particular schedule does not establish a statistically significant DCS incidence. Only on completion of the study can this be estimated by looking at the results of all the schedules which were tested. In the end it is usually necessary to restrict analysis to a particular depth/time domain and look at the incidence of DCS within that domain. A DCS incidence of 0% within that domain would be ideal but is usually not attainable in a reasonable number of dives. In practice, if the overall expected incidence at the 95% confidence level is less than 4% as a result of a validation dive series the decompression tables are recommended for Fleet use (within a specified depth/time domain) providing that the DCS incidence was uniformly distributed over the proposed depth/time domain. If, however, the overall expected incidence is lower than 4% but most of the DCS occurred during a particular type of diving, say repetitive dives, then additional testing would be required before a recommendation for approval of the repetitive dive procedure was given.

The above criteria is based on a single model being used to compute all tables. The assumption is that the risk of DCS will be fairly uniform throughout the depth/time domain to which diving will be restricted based on testing and that the overall DCS incidence during testing gives an upper limit to the overall risk of using the model.

Realistically, recommendation for Fleet use must be sought when it has been established that the DCS incidence will not be excessive and that if DCS does occur it can be easily treated. Resources are usually not available to do the thousands of validation dives to establish a statistically significant DCS incidence for each and every published schedule. It is accepted that only during operational use will the true DCS incidence be established and if unacceptable then the procedure must be modified. Table validation in reality is an ongoing process. In the USN, the Navy Safety Centre in Norfolk receives the results of all dives so the actual DCS incidence can be monitored retrospectively.

Subject Selection: In NEDU studies subjects are randomly selected from the USN diving population. While no specific physical selection criteria is used, one can assume that all of the subjects are in good physical condition. Subject age in recent NEDU studies (33, 34, 35, 36, 38) ranged from 20 to 38 years and experience ranged from those who dive almost constantly in their normal time of duty to Officers whose diving intensity may have been as low as 1 dive monthly.

Diving Intensity: Based on the constant 0.7 ATA PO_2 in Helium studies (35) a 48-60 hour interval between successive dives for a given individual should be used to minimise acclimatisation. However, even with this diving intensity, at least two or three of the resultant decompression tables should be tested on a set of fresh divers who have had no pressure exposures within the past week to ensure that they are in fact safe for acclimatised divers.

Environmental Conditions: All dives should be done with divers exercising at depth and resting during decompression these conditions have been well documented as maximising decompression stress (3, 47). The exercise rate should be the upper limit of what a diver would realistically do operationally. In the recent NEDU studies an alternating work/rest cycle was used with divers attaining an oxygen consumption of 1.6-1.8 l/min for one half of the bottom time.

The effects of immersion and water temperature are more controversial. Evaluation of the DCS incidence of some North Sea Diving firms established a link between cold water and

increased incidence of DCS (41) but a more recent study suggested that warm divers wearing hot water suits were at more risk (47). If one believes gas uptake and elimination increase in warm divers and decrease in cold ones, one would have divers warm at depth and cold during decompression to maximise decompression stress. Since the no-decompression limit depends almost solely on gas uptake, then one would expect a higher DCS incidence in warm than in cold divers for no-decompression dives. During one NEDU dive series (35) no difference was found in the DCS incidence for wet suited divers in warm ($71^{o}F$) versus cold ($45-55^{o}F$) dives. This was based on 1 DCS in 57 man dives at $71^{o}F$ and 2 DCS in 66 man dives in cold water. While controversial, the author's opinion is that chilled divers have a higher risk of DCS than warm divers and that this condition should be used during testing of tables, until the evidence clearly demonstrates otherwise.

The evidence on immersion is also controversial. Operationally, immersion and cold stress generally go hand in hand so separating the effects of these two variables is difficult. Van Der Aue saw no difference in DCS incidence between wet and dry dives (3). The problem is that these were surface decompression dives with most of the decompression being done in a dry chamber. Rubenstein (22) cited a personal communication he had received which stated that dry dives were as stressful as wet dives if exercise was done at depth. In a recent NEDU dive series (36), two dry tenders experienced DCS on dives were no DCS occurred in the cold wet divers. This would imply that being warm and dry does not necessarily confer one with an overwhelming advantage as far as DCS incidence goes.

The evidence suggests that while immersion may not be worst case it certainly is not advantageous. Until it can be firmly established that dry chamber dives are more stressful than wet diving, validation dives should be done wet to simulate operational conditions as closely as possible.

Breathing Gas: As a general rule decompression tables should be tested using the same inert gas and PO_2 in the breathing gas as will be used operationally. If a particular procedure is designed to handle various PO_2 levels, then the procedure must be verified over the PO_2 range to be used. This was done by NEDU in evaluating a computer algorithm's ability to compute real time decompression schedules when switching between various PO_2 levels supplied by air and a constant 0.7 ATA PO_2 in N_2 (36). One must be careful, however, not to use a model to validate itself. As an example, using various PO_2 levels to simulate theoretical inert gas uptake at depth deeper than the actual depths cannot take the place of dives to the actual depth unless the investigator can show that it is a reasonable simulation.

Table Adequacy Criteria: The most common methods of evaluating decompression table adequacy is the clinical incidence of DCS. This has been used in most NEDU studies were all signs and symptoms have been analysed first hand by a Diving Medical Officer. Tables which produce no symptoms, however, are troublesome because there is no agreed upon way to compare their decompression stress with other asymptomatic tables.

The Modified Snyder Score previously discussed (15, 17, 21) provided gradings for minimal symptoms but gives all symptoms equal weight and assumes a certain heirarchy of symptom seriousness. Decompression tables with scores 5 or greater (Table 4) would be clearly inadequate while those in grade 1-4 would still require a considerable amount of judgement in deciding relative decompression stress. Altitude provocation as discussed earlier (18, 20) was an attempt to rank asymptomatic decompression schedules by evaluating the response to the additional stress of reduced ambient pressure (Table 3). Although this may seem attractive theoretically there are two major drawbacks. One is the necessity of having and manning an altitude chamber at the dive site. The other is the risk of taking an individual who may only be at risk for pain only DCS at 1 ATA and exposing him to the possibility of developing much more serious symptoms at altitude.

Certainly the most discussed method of evaluating decompression tables has been the Ultrasonic Blood Bubble Monitor (or Doppler). During the most recent NEDU dive series (34, 35, 36), Doppler monitoring was done after all dives using the K-M score according to the method used by DCIEM (43). Monitoring was done 5-35 min post dive, 60-90 min post dive and thereafter as indicated. Well over 3000 measurements have been done but were not used to make decisions regarding table adequacy or the necessity for treatment but were only looked at retrospectively to see if the measurements correlated with clinical observations and DCS incidence. The results have been disappointing. In one series of HeO_2 dives (35), a series of sub no-decompression dives decreased the DCS incidence on a 120 FSW/40 min schedule from 5 cases in 11 man dives to 3 cases in 31 man dives with no change in overall Doppler Score (37). Analysis of this data continues.

One might adopt the attitude that only decompression schedules which result in no detectable bubbles should be considered adequate. First of all there is no evidence that the detection of venous bubbles in otherwise asymptomatic individuals is harmful, and in fact the author has seen DCS in individuals with no detectable venous bubbles. Second, in the author's experience some individuals are more prone to develop intravenous bubbles than others, and decompressing these individuals without causing bubbles may result in exceptionally long decompression schedules.

The next option is to not accept decompression tables which give rise to bubble scores above a certain minimum in a certain percentage of subjects. The author's opinion is that this will also give rise to a certain number of symptoms of decompression sickness which will provide as good an analysis of table adequacy as the Bubble Score.

Until a method for using the Doppler is developed which has a high correlation with the incidence of symptoms of DCS it will not replace the bends/no-bends criteria currently used. Published articles

to date have not demonstrated such a correlation (44, 45). Careful clinical observation is the best method of evaluating decompression table adequacy as long as all symptoms, no matter how minor or trivial, are recorded and evaluated first hand by trained and experienced medical personnel. Minor symptoms such as fatigue or transient niggles must be considered as they probably indicate a higher level of decompression stress than completely asymptomatic tables as pointed out by Molumphy (7). These minor symptoms are useful in deciding if the single overt case of DCS in 20 or 30 man dives was a random occurrence or the result of a marginally inadequate schedule. Absolutely no minor symptoms (rash or fatigue) in any of the other subjects would suggest the former, while a degree of niggles and fatigue would suggest the latter.

In summary, clinical evaluation of all post dive symptoms, no matter how minor, is probably the best method of evaluating decompression table adequacy. More experience using the Doppler to evaluate intravenous bubbles is needed before it can replace clinical observation.

CONCLUSIONS

Validating decompression tables or procedures remains a matter of subjective and objective interpretation of the results of manned dive series. Tables must be tested under conditions which closely mimic actual operational conditions and worst case combinations of environmental variables should be used where known. When dive data from other workers is used to validate a decompression model it must be verified that all aspects of the conditions and methodology used to perform the dives is know. Investigators are required to produce results which demonstrate that there would be no undue hazard in using the recently validated tables operationally and the users must realise that heightened precautions to deal with the possible occurrence of DCS is required until a substantial amount of operational experience has been accumulated on new tables.

Ongoing evaluation of decompression procedures must continue and methods should be at hand to systematically modify field procedures to increase safety if needed. In evaluating decompression table adequacy, all signs and symptoms of DCS should be seen and documented by trained, experienced personnel. At present, the use of the Doppler monitor to evaluate decompression stress should still be considered experimental and probably provides no more information than the evaluation of clinical signs and symptoms.

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ADDITIONAL COMMENTS BY CAPT THALMANN

As usual with these talks I have to throw in the familiar disclaimer that all that I have to say is my own personal view. Let me stress a few points. First, the Navy has no specific policy in validating tables. It is generally up to the individuals who have been tasked to do the study.

In the HeO_2 part of the 0.7 PO_2 algorithm development, we ran into the "work-up" phenomenon again. After doing 1200 man dives we thought we had a set of tables, which we actually had all nicely packaged ready to send up to Washington. We did some dives to just kind of recheck them on a profile which had had no hits in 40 man dives, which I think most people would have considered a safe schedule. And we bent 7 people out of 19. This obviously caused us to do a lot of backpedalling; we managed to reduce that bends incidence to 3 in 31 by doing a bit of a work-up procedure. This established in our mind that what we had done inadvertently was worked our divers up.

About susceptibility, we generally will not take somebody into a study that has a long history of getting bent. I mean, if you are doing an experimental schedule evaluation the object is to make tables safe for most divers, and you may wonder, why not?

Our experience is that these individuals may be at a much higher risk for permanent damage than other individuals. In the course of doing a dive series, it may become evident that certain individuals are getting bent more than others. By and large they will quit, which solves everybody's problem. If they do not, we generally have a talk with them and get them out of the study.

Why do we do that? Because if you have done 100 man dives and you have had 5 hits and they are all on the same subject, then you conclude that this individual is susceptible. This has happened on every dive series we have done, and we just have to live with it. There appears to be no way to detect these subjects in advance.

Then you might say, "Well, what happens when this guy goes out and dives these tables operationally?"

Well, that is another problem. I personally have counseled a couple of divers and advised them that maybe they should consider another profession, simply because their incidence of bends is significantly higher than the population they are diving with and the tables are not necessarily meant for them.

And it is also our opinion, based on a few cases, that these individuals may have a higher probability of suffering permanent injury if they do get bent in the future.

I have to say also that when the Navy develops a set of tables, they develop it for Navy use. That may be pretty hardnosed to say, but that is what it is all about. In that development, they are very much influenced by the Navy system which includes diving medical officers. It includes chambers. It includes evacuation systems, etc. Therefore, in assessing the need for further table tests you are looking into that whole system to decide whether or not you are developing a set of tables that is going to hurt somebody, and whether or not the system can take care of it. Generally, the system is not too upset by Type 1 decompression sickness. It is very upset by Type 2. So, the raw bends incidence kind of gets muddled. And then you have to decide what raw bends incidence you are willing to accept before recommending tables for operational use. There is only so much time and effort which can be put into table testing. If you look at Tables 1 and 2, or even better the original reports, you will probably see that most of the tables have been recommended after between 800 and 1200 man dives. The bends incidence was running about 3 to 4% even after we had restricted depth time limits of the table. Within a reasonable amount of time and effort, there was just no way to get it any lower than that. Based on that, we had to decide whether it was reasonable to recommend the tables for fleet use or not.

But, the tables are followed up. When they are initially put out to the Fleet, there is a heightened awareness, and we do go back and look to see if there are any problems. We are working on the naive assumption that the more they are used, the lower the bends incidence gets. If we see that the more they are used, the higher the bends incidence gets, we will go back and have another

look at them--like we did with the unlimited excursion tables.

So, the validation does not stop at the laboratory. The only thing that we hope to accomplish in the lab, if you will, or in the chamber dives, is to establish that the tables are safe enough to go out to the Fleet and that we are not going to get a lot of Type 2 bends. At that point it is time to put them out to the Fleet so we can rack up the 10 or 15,000 man dives that we really need in order to decide if we have hit it or not.

VALIDATION OF DECOMPRESSION SCHEDULES-THE OPERATIONAL APPROACH

R.H. HOLLAND - CORPORATE SAFETY DIRECTOR

Introduction

After 35 years practical involvement in the diving industry, formerly with the military and latterly commercially, it is remarkable that any dilemma should exist in my mind as to the parameters which should be applied to the validation of new decompression schedules.

Having experienced at first hand the efforts of our scientific community to produce new schedules, often from new and revolutionary models, by participating as a test subject in field trials, after simulated dives in laboratory conditions, it can be fairly said that laboratory proving does not automatically ensure acceptable operational performance. On the other hand without laboratory testing in those earlier days, the "experience" during field testing would have been infinitely more painful. With the development of computer technology however, the potential is there to evaluate schedules to such a degree as to substantially reduce the importance of the laboratory test and produce viable procedures which should require only fine tuning when exposed to the operational environment.

The ever developing litigious climate within the diving industry has contributed to the need for more reliable schedules in addition to the obvious grounds of efficiency and ethical considerations. At the same time this litigious climate has had an adverse effect on the introduction of new operational schedules until their reliability can be established beyond doubt. The earlier approach of "bend them and treat them" is no longer available.

In order to establish this reliability it is necessary to have a generally accepted list of criteria on which this validation can be based, the absence of which creates the dilemma.

Validation Criteria

The following criteria form a basis for consideration:-

Incidence of Decompression Sickness

Various incidence or probability of decompression sickness have been quoted, sometimes as high as 5%. For commercial operational purposes 5 bends in every 100 dives is totally unacceptable. Even one bend in every 100 dives (1%) must be regarded as poor performance compared with experience of currently used procedures.

An overall incidence of less than 0.5% is achievable operationally and must be the minimum target. A procedure of higher incidence than this would be inferior to most currently used decompression procedures and carry an increased exposure to litigation, making it of no interest.

Spread of Decompression Sickness

While an overall target of less than 0.5% may sound reasonable, it is of equal importance to evaluate the spread of those incidents over the depth and time range of the schedules. For example, with some air diving schedules, reliability at depths less than 100 feet is considerably better than in excess of 100 feet. Performance also deteriorates as the bottom time increases and it is possible to identify certain depth/time schedules as high risk. These areas of marginal performance must be evaluated to bring the DCS incidence within a reasonable target.

Type of Decompression Sickness

The overall target of less than 0.5% is of little consequence if the DCS involved results in a majority of serious manifestations. Pain only and other minor symptoms give rise for less concern and can be treated successfully and simply if reported early. Serious manifestations involving the central nervous system have a higher potential for residua and long term decrement in CNS performance. Serious DCS must be at the absolute minimum incidence and where practical avoided at all costs.

You will note that I have refrained from using the DCS classification Type 1 and Type 2 when mentioning pain only and serious DCS respectively.

This is because the classification "Type 2" is used to cover such a wide range of symptoms that it is often inappropriate. While some of the symptoms used to categorise Type 2 DCS are life threatening with a high potential for residua (serious), other symptoms are far less serious with little risk of residua. In this respect it is desirable to use another method of DCS classification in order that the validation of a decompression schedule is more closely related to the seriousness of any DCS involved.

Practical Viability

While decompression procedures can be designed to operate effectively in the laboratory environment it does not necessarily follow that they will be effective operationally.

It is important that to be considered viable for say an offshore operation the following factors must be considered:-

1: Training and experience of the diving supervisors and divers who will use the procedure. With bounce diving techniques particularly it is essential that the decompression profile is simple to follow and that any gas switches are practically possible. Complex procedures of gas changing and short decompression stops can put a diving supervisor under extreme pressure and lead to errors of procedure.

2: Limitations imposed by requirement to switch gas during decompression. While gas changes may be desirable to assist in inert gas elimination, the logistics and effect on deck loading of the various gas mixtures required at the site must be considered. Availability of pre-mixed gas in remote areas is also problematic and may necessitate on-site gas mixing.

3: The wide variation in operational conditions under which the procedure must be used.

Examples of these variables are:-

- Work load variations
- Ambient sea temperatures
- Heated and unheated divers
- Maintenance of temperature during decompression
- Frequency of diving
- Overall working environment

Factors such as these have a major influence on the success or otherwise of dives which, when simulated in a laboratory may have been trouble free yet develop problems when used operationally.

4: Necessity to have a background of credibility in order that if a lawsuit does arise, which can be related to a decompression procedure, it can clearly be established that the procedure is based on sound principles and is a reliable alternative to other procedures available. It may also be necessary to prove that sufficient experience exists with the procedure to establish that it is operational and not experimental. This poses a question as to how many dives must be made before a procedure can be classified operational.

Those conflicts generally preclude the introduction of new procedures into the U.S. offshore environment until extensive experience has been gained in other less volatile geographical regions. This can be to the detriment of the safety of the U.S. diver, particularly when a new procedure is obviously more conservative or safer than existing currently used procedures.

The trend for even minor incidents to result in a lawsuit is spreading steadily to most regions of the world. This trend is having an inhibiting effect on the introduction of new procedures until a high degree of confidence exists that performance will not deteriorate significantly in the field.

5: What, if any, is the overall effect on the working efficiency of the diving procedures? Moderate extensions to the total decompression times are less critical than reductions in effective working time of a dive.

Increases in available working time are welcomed by the Client but if available bottom time is to be reduced there must be strong underlying safety reasons to support the reduction in productivity.

Introduction of New Decompression Procedures

With safety as one of the prime operating criteria within Oceaneering, there has been a continuous effort by the Safety Department to improve decompression procedures and thereby reduce the incidence of decompression sickness. The improvement is reflected in a decrease in incidence of DCS from 0.421% in Fiscal Year 1983 to a rate of 0.146% in Fiscal Year 1986 and year to date 1987 for all modes of diving.

Air diving has improved from 0.4% in 1983 to below 0.15% for the last two years as a result of replacing U.S. Navy dive procedures as printed, with extensive modifications and in some cases additional procedures for special operational conditions.

In order to assess the reliability of one procedure against another, a comparison of the profile is made between existing procedures where the performance is well recorded, and the

"new" procedure. Although not very scientific, this can give some indication in the absence of a more finite method of assessment.

If a procedure is considered to be an improvement on an existing one, or have desirable features for a particular application then it is introduced on select operations and its performance monitored on a dive-by-dive basis. As the performance is established and confidence grows, other operations are included on a progressive basis until it becomes a regular company procedure.

During such evaluations, it is important that recording is precise and accurate. To this end it would be desirable to use depth/time profile recorders as the fallibility of the hand-written dive record must be recognised. As these devices are developed and become more efficient and readily available they will become an essential element in the practical validation of operational decompression procedures.

Any incidence of DCS is investigated in detail to ensure that procedures have been followed and that the incident is not a result of a deviation as is sometimes the case.

Pre-Operational Validation - Future

Although computers do not always produce a complete answer when used to produce decompression schedules, this is really related to the quality of the input information or the model to which they must work.

They could provide a very effective tool for the validating of new procedures in the future by comparing various elements of known performance schedules with the new procedures. For instance, using the U.S. Navy Air, Modifications to the U.S. Navy Procedures, Norwegian Underwater Institute Modifications and say DCIEM tables as a basis of experience, any proposed new procedure could be measured against them by means of a computer evaluation. Such a system would remove the more subjective evaluation/-comparison previously mentioned. Using the U.S. Navy Procedures as the minimum standard would ensure a performance level which has been accepted by many commercial companies over the years.

By evaluating various critical factors of a new procedure against these proven procedures, the degree of confidence when introduced operationally would be improved and credibility enhanced. Such validation could also reduce the number of laboratory simulations required.

In the U.K. validation parameters for Air Dive Procedures has taken on even greater significance recently with the introduction of Diving Safety Memoranda No. 7/1986 - Exposure Limits For Offshore Diving.

To avoid the very severe limitations imposed by this memoranda it is now necessary to submit company procedures for consideration as being safe before dispensation may be granted to exceed the defined bottom time limits.

The memoranda was produced as the result of a survey commissioned by the U.K. Department of Energy which reported on the incidence of decompression sickness related to air diving in the U.K. Sector of the North Sea. The report based on 25,000 dives in the period 1982/1983 indicated an unacceptably high incidence of Type 2 DCS and also a probability of a further increase when using actively heated hot water suits on dives with long bottom times. This has led to some very innovative thinking by diving companies to produce procedures which will convince the diving inspectorate to grant these dispensations. The review of the procedures is being made on records of experience submitted, but the evaluation could be greatly simplified if a computer could be used in the manner previously mentioned.

In summary, the offshore diving companies must exercise caution when introducing new decompression tables for commercial use. In the absence of any validation criteria which can be generally applied, they must measure and validate new procedures against their background of experience with the procedures they currently use. The origin or source of any new procedure becomes a criteria on which a degree of confidence can often be based and becomes an important element in establishing its credibility.

Despite the subjective nature of these methods, our own experience has been good in improving the overall safety of our diving operations. In many cases operational efficiency in terms of working time at depth has also improved. It should be noted that the new procedures are generally modifications or adaptations of recognised techniques and procedures, which simplifies any validation. With totally new concepts a more detailed procedure of validation is required prior to any field evaluation. Hopefully computerised techniques will be developed to facilitate this function but in the absence of such a system the only alternative is laboratory testing. It is hoped that this workshop may be able to produce

some guidance on a formula of numbers of laboratory dives, before operational validation should be considered.

The effect of the legal climate on the introduction of new procedures must not be over emphasised but it has to be considered. Conversely, the introduction of new safer procedures can have a positive effect legally by reducing the number of law suits. While some of the "experts" used in these suits are prepared to adapt their evidence to satisfy their paymasters a risk will exist whatever procedures are used.

The U.S. Navy Procedures form the basis of many of the currently used commercial diving decompression procedures. It is of credit that these procedures, although originally designed for military purposes, have performed so well commercially, but by modification their performance can be further improved. To this end no constraint to use these procedures is felt, but they still form a yardstick by which many new procedures can be measured.

It is difficult to accurately evaluate the performance of one commercial company's decompression procedure performance against another due to confidentiality, and in some cases different reporting formats. From the recent U.K. study however, there are indications that there may be small differences in performance, but with air diving the total DCS rate is relatively low. With a total of 35 "Type 2" classification DCS incidents in 25,000 dives this may be a weakness in some procedures. Some companies have probably improved their procedures since the period included in this study (1982/83) but it is an area worthy of monitoring.

Arbitrary modifications to procedures are discouraged in the field whatever the experience of the diving supervisors and divers. By working to published procedures and monitoring dive records, problems can more quickly be recognised and modifications introduced for the benefit of all operations.

Modifications to existing procedures have proven effective in the past but the introduction of a completely new format of decompression procedures would be considered. Work is presently being carried out which aims at a new concept of multiple depth exposures and this development will be monitored closely.

During offshore evaluation every effort is made to ensure that all personnel are briefed in detail on the use of new procedures.

Any incident results in the suspension of the evaluation until such time as investigations have been made and conclusions reached.

Genuine efforts to improve the safety of decompression procedures generally have the complete co-operation and support of the divers. The decision whether to participate in a procedure evaluation is left entirely to the individual.

Any guidance or validation standards which reduce the present speculative nature of assessment today must be an asset. The industry has managed very well to date but there is always room for progress and improvement.

ADDITIONAL COMMENTS BY MR. HOLLAND

Let me embellish a couple of points. Many of you know this--especially in America, and certainly our lawyer knows it--but we unfortunately see some cases that are suspect. I am sure many of them are very justified and have good reason why the people should go to litigation to get a settlement. But amongst them, I am afraid, these days there are an enormous number of suspect cases. We no longer see the person get over a simple bout of decompression sickness completely. He usually comes back afterwards and puts one in for the judge's bundle that he has become irrational at home or gotten grumpy with the wife and it is the long term effect. He probably is just preparing it for later on when he can get another event to turn it into an early retirement plan. Obviously, we have to prevent that. This is why we so badly need criteria for validation.

The next thing is diver heating. I would like to say a little thing about that because this has been getting a little bit blown out of proportion recently. I believe, personally, that diver heating, does have an effect. We have seen it on operations where we have used the procedure many, many years in the particular depth-time range without diver heating, successfully. We then go to another area of the North Sea where that particular country insists you use diver heating for whatever length of dive. We brief the divers before they go: "Keep the temperature down. You are not meant to be down there in a hot bath, just to keep the cold away." But some of them like it that way so, up goes the bends rate.

But it may not be just the hot water suit that is causing it. I believe perhaps that the hot water suit does increase the gas uptake, as Dunford and Hayward mentioned in UBR many years ago (1981; 8:41-49), but I do not think it is that. I think it is the problem of warmth during the decompression. If the man is going to be very hot in the water, we have got to maintain that temperature level throughout the whole length of the dive, right through the decompression as well.

In many instances these divers are brought up to an air dive DDC, and if you look at some air dive DDC's around the world you see just a can with a couple of pipes running in and out and probably a bullhorn. But, really, you have to have heating in the DDC, so that during his decompression he is warm.

After we put a heater in the DDC's the bends rates went down. We had 700-odd very high stress dives in the 140 foot range. We had 5 bends in the first 200 dives and we had 1 "suspect" in the next 700.

Regarding the Diving Safety Memorandum 7/1986, that report, suggesting that the Type 2 DCS was far too high and there was a target of zero for Type 2 DCS, has a number of important effects. First of all, the clients scream their heads off. All of a sudden, they did not have the same bottom times available to them. Secondly, I think that with the contractors wishing to get the work from the clients, they are going to make sure that they do not have too many Type 2 DCS's. Now, there are going to be some rather squirrelly shall we say? "Assessments" of what a bend is. We know we are going to be in real trouble if they have to make a differential diagnosis, because you can bet your tail that they will be saying, "That's a pain-only bend." The guy will be rolling around and probably can not see straight, "but he has a pain, let us call him Type 1." It is a bad situation, really.

How can the diver's share of the risks be established? There is no means of establishing that risk. With the best table you have you suddenly come up with a full-blown bend of a serious nature. You just cannot predict. It is still something we are in the dark about.

As to whether a uniform standard or consensus on the validation of company-produced tables could be of value, I think they would. I think it would be nice to have some standard to work toward. You may have trouble getting all the industry to accept it. But it would be helpful, for instance, if a legal case come up, if a table had been validated to some particular standard. You would have a little bit more strength and it would support that you were not being immoral or whatever they want to call it and putting your diver at undue risk.

MINI-PRESENTATION: A VIEW FROM A U.S. DIVING COMPANY

Andre Galerne
International Underwater Contractors, Inc.

It is very difficult to follow Dutchy's act. I am perfectly agreeable with all his conclusions. I was surprised to hear that 1% or more was acceptable as a test for a decompression table; I guarantee that we will not survive in a diving world if we were to have this level of accidents constantly.

It is true that it is very difficult to test new tables here in America because we are very sensitive to lawsuits. With the Jones Act it will be very difficult to go in court to explain to a judge or jury that we have done all of our homework and decided on a table that has not been tested. So, we have to be excessively careful.

Fortunately, directly on the job site, on the professional job site, we practically have no problem with diving accidents because we have a recompression chamber on the spot and the people are trained to immediately recompress the divers and really treat them. In fact, I do not know of a case in my organization where we had a case of bends or decompression accident which had not been completely treated on the job site.

If you treat a bends and decompression case in five minutes of the first symptoms, you are practically assured to be clear. The impossibility is the diving accident they bring you three, four, five days later or sometimes only a few hours. So, we are not too scared of decompression accidents on the job site because we have the equipment on hand, we have the people who know how to use it and if we have an accident we take care of it immediately.

I am speaking mostly about construction diving. Funny, when you speak about construction diving, people think you are only working in 5 or 10 feet or maybe 30 feet of water, which is true. We do a lot of that.

But we do also a lot of work on things like hydroelectric dams, where we are sometimes 200, 300, or 400 feet deep. And we have to do heavy construction on the bottom, which is not always easy.

When I came to this country in 1962 I was looking seriously at decompression tables. I was not too happy with the U.S. Navy decompression table. We have done our own tables. I have been working very hard on trimix. Our company started diving with nitrogen-oxygen-helium in 1964. We have been very happy with trimix. In fact, we use trimix on dives to 650 feet. And no bends. They are painful tables because they demand long, long decompressions, but it can be done.

I think it would be good to have better coordination with research. I see this morning, for example, research done on helium at 120 feet. I am sure this is very interesting to do, but from our point of view, we do not use helium at that depth. We start to use helium much, much deeper. But I think you know a practical reason for our point of view; we will be better if we can coordinate and the results of research can benefit everybody.

I will give a few tips as to how we manage some of our problems on the job site. At one point, when we started to experiment with new tables, we had some incidents and we looked for a solution. We tried to modify how we used the table, which can influence the table's results.

For example, in reviewing a job done by Behnke in 1931, I saw that he made some measurements showing that CO_2 was capable of being eliminated from the body in less than one minute. So we decided that at the end of each dive, we will relax for one minute. We do not move. We do nothing. We relax and eliminate CO_2. We feel that CO_2 could be responsible for a decompression accident by being a very unstable gas producing the first bubble, and leading the decompression which later on provided the accident. We tried that one-minute rest and we were happy to see a decline in our problems.

We have also had some surprises. For example, we discovered when we were diving with a diving bell in very cold water, the divers were not bent. It was tenders in the bell. The tenders, although they were not deeper than the divers, gave us more trouble than the divers.

Well, we studied the problem and we saw that the diver had his cold water suit and his body

was not exposed to any helium, therefore, the skin was not used as a breathing organ. In contrast, the tender is stuck inside the bell and was taking in some gas through his body. And now we look more at the table for the tenders than for the divers. This is a practical thing, you know, which we have found that by doing our job.

For example, when we do the recompression technique (sur-d), we do not use the regular technique. We decompress the man to the surface after the necessary stops in the water and then we recompress him to 60 feet with chamber. We then treat him with oxygen as if there had been decompression sickness. We do not go back at 30 feet or 40 feet or 20 feet. We go back to 60 feet, systematically, then treat the guy.

We have found that to be a pretty efficient way to avoid any trouble with the recompression technique. We have been very happy with that.

I am happy to see the report of my friend Dutchy that the government gives them trouble, because if we do not do that ourselves in a few years we in the U.S. will be second class citizens in diving. They do a lot of research and good work in North Sea which we do not do here in this country because of lack of funds.

If we do not change that, as I said to my friend Tony Calio (NOAA Administrator) some time ago, in less than five years we will go back to Europe to buy our technology. It is appealing to see that your (European) regulations cut you down and pull you back, otherwise we have no chance. But if they cut your bottom time to 30 minutes, great. Because, at the end, you know, in the construction business or in the diving business, we pay the diver the same price if he works 15 minutes, 30 minutes, 75 minutes or 90 minutes. In research, you know, the bottom time is really the time that counts. The customer pays for that time. He does not pay for the time you are in the diving bell or on the surface decompressing. So, in our business, regular time at 200 or 250 feet, it is normally 75 minutes or 90 minutes per diver. We cannot afford, at the price we pay the men, to have them working only 15 minutes. It would be counterproductive.

My last point is the problem of the expense of insurance, which is suppressing the use of divers. We are now seeing the use of ROV's, more or less sophisticated. Before, in each exploration rig we had a diving team working. Now, forget the diving team in exploration. It is automatically the ROV's only. The oil companies are under the control of the lawyer, which means, they prefer to spend money or lose money, but not have a lawsuit. So they say, "We do not want to hear about men under water." And it is absolutely essential that we find a way to justify, after all, that when a man is hurt on the job the Workman's Compensation will take care of it. In the diving industry--we are the only industry in America like this--an employee can refuse Workman's Compensation and sue his employer for negligence. And believe me, it is very difficult to prove there is no negligence when you do a job. A drop of oil on the deck of a ship and the ship is not seaworthy any more. And if the ship is not seaworthy, you pay. You pay the bill.

We have to find three solutions. Technically here with you, the doctors, the specialists in diving medicine, we need table validation criteria to improve our position. We also have to find a solution with the law, the Jones Act, or better with legislation. And we have to find a solution about using man or not using man.

DISCUSSION AFTER MR. HOLLAND AND MR. GALERNE

DR. ELLIOTT: One question I have of Dutchy. The Department of Energy has sent out a call for tables to be submitted that are safe. Are these tables kept in confidence by the Department of Energy?

MR. HOLLAND: Yes, they are kept in confidence. That is rather strange, their coming to the decision to give dispensation to use tables, but they do maintain confidence from company to company. So, if you, in actual fact, were to submit a number of tables that are not favorable to them, you could probably get a negative response. Whereas, if you put in tables which even may have rather a dubious background but they favor them, you can get the dispensation. "Validation" would be helpful because all of us would be assessed under a fixed standard, not a whim.

As I say, with the greatest respect, the DCIEM table is accepted. Now, I am sure it is an

excellent table; I am not trying to discredit the table. But the fact is we are getting dispensation to use that immediately without any previous experience offshore for that particular table. Yet, this is in preference to other tables that we have used which we know to be more conservative--viz. the Norwegian, I think, would be a fair instance, and the Comex table.

DR. ELLIOTT: The closed meeting for the Department of Energy inspectors, the diving industry, decompression people like Tom Hennessy plus members of the Diving Medical Advisory Committee had a good discussion. It was a closed meeting, but I would endorse what Dutchy has said.

CHAIRMAN SCHREINER: So, you are signaling a need for more objective acceptance criteria by an agency like the Department of Energy, based on some known criteria, some known requirements.

MR. HOLLAND: I think it just highlights the very reason we are sitting right here today. It would be nice for the companies. More importantly, we have a government agency that has gotten itself into a position, after having reacted to some information in a report which could well be criticized, and now they do not know how to go to get themselves off the hook.

MR. IMBERT: I would like to make a comment on commercial diving. The character of diving activities has changed in the '80's. There are many reasons why. The first one is that a new field has been opened in the shallow water depth like in the Middle East and Far East. Second, the activity has changed; 30% of the activity now is inspection, repair, and maintenance, which is shallow. And the last one is that the market depression leads to the low margin contract. It is a new phenomenon.

We do a lot of diving. We are going to do more and more of it. And we need tables. We need long bottom times, especially in the shallow area, because like for our welding operation, depending on the size of the pile, we may need two or three hours at the bottom before we finish the first and second pass. This table is not yet available.

Secondly, since it is new, we need to document the purposes of our table. DOE has reacted in a positive way by making people show their statistics. It looks different from what we have seen before, especially from U.S. Navy tables. So, I think for the subject to be brought to discussion openly and freely is very positive. Not too much for the existing tables, which were the basis of the development of commercial diving. They were available first, they were available to everybody, and they were certainly the best available in the '70's.

Nowadays we are identifying some of their shortcomings. First is the safety, and even risk distribution. Secondly, very little is being said about emergency procedures, repetitive diving and so on. If the U.S. Navy is not able to provide new tables, if governments are not able to provide the tables, it is up to us, the diving companies, to find ways of improving and adapting what exists, and to bring new tables up to the required standard. I was glad to hear that you have been using this sort of empirical approach with modification and adaptation in order to provide efficient tables appropriate to the need of the commercial work site.

MR. HOLLAND: I agree with you. I think a fair indication of that is by trying to get these extended bottom times through the use of nitrox [enriched air]. There is a readily available mixer on the market that you can use to mix gas [oxygen and air] as you require it. We are extending our bottom times by using this, particularly in shallow dives where we want a long time to weld a particular job. We are extending our bottom times by using nitrox, reducing the equivalent air depth and on no-decompression dives getting quite long bottom times. It has been working very successfully.

CAPT THALMANN: First two comments. I would like to ask our commercial colleagues to write down on a piece of paper and submit to this workshop exactly why Navy divers somehow are different from other divers. The statement is made that Navy tables do not suit the commercial companies' needs, which is a bunch of baloney. A diver goes to depth for a certain period of time and has to get back to the surface safely.

So, when somebody says that Navy tables do not consider needs, that means to me one of two things: Either Navy divers are different--which they are not--or simply that the commercial companies want to dive outside the range of the tables. Then they think the incidence is too high.

I think they really ought to be specific about exactly when U.S. Navy tables do not apply to the operation rather than making a blanket statement like that, which is pretty much wide open.

My second comment has to do with the way the commercial companies go about evaluating tables. It is very nice to say, "We have got 30,000 man dives here and the incidence is 1 bend in 10,000. But that is unacceptable and we would not accept a table which comes out of a laboratory which has a bends incidence of 5%."

The problem is that all of the work that is been done at EDU in the last 10 years is documented, is available. People have access to it. The bends incidence are identified. If you go into the data, you can see who got bent on what dive, who the repeaters are. There is no such data base from the commercial companies.

So, if the commercial companies are going to get up there and continue to say that these procedures are not applicable, then I think it is their obligation to lay their tables on the table, as it were, say what they are diving, how they are diving and what the real bends incidence is.

If you read the Shields report [Ref. 42 of Dr. Thalmann's talk], the one thing that comes out which probably points up the way commercial divers are at all, is that the companies would not even allow them access to enough data to determine how many repeat bends there were.

Now, how can you do a sane analysis on anything unless people are willing to put their data on the table? It is the military which is spending the disproportionate amount of money developing tables. As a specific example, the 0.7 HeO_2 tables are already being adapted to commercial application, without them having put one cent of development into it and, yet, it may very well be that once the field experience is gained in these things, that they are unwilling to feed back to the U.S. Navy and say, "Listen. We have adapted your tables to this particular application, but we are not going to tell you what they are." So, it has not really been a two-way street as far a transmission of data.

[EDITOR'S NOTE: Dr. Shields made the initial decision not to know individual divers *himself*, and asked that their identities not be given by the companies. In later work this has been known.]

MR. HOLLAND: Okay. I hear what you are saying. I hope I have not been understood as saying that the U.S. Navy divers are any different from the commercial divers. I do not think they are for one moment. But we use the tables differently and probably in different ranges to what you normally do. Someone mentioned this morning that the average depth for the air diving in the U.S. Navy is 40 feet. Ours is about 85, 86 feet. So, we are using them in different depth ranges and probably under different circumstances.

I am not saying the divers are any different because a lot of ours are ex-Navy divers. So, I mean that was not implied, I hope.

As far as talking about the Shields report, Shields might have had difficulty with some companies. He had every dive log, the actual dive logs, from us. And he was able to analyze them as he wanted. There was no restriction put on him and we had said we are quite happy for him to publicize whatever data he takes out of our logs, provided the other companies will go along with it.

Unfortunately, when these things are put out, other people try to use them for commercial gain. If you wanted to see the dives we do, I mean the dive-by-dive record, we would only be too glad to show them to you. So, what we tried to do, I think, was to modify the U.S. Navy tables in such a way that coped with the environment in which we work. I said at the beginning, some of those things probably could be considered tables of "boost." We are pushing the tables unmercifully. When we have two repeats in a short period of time, sometimes we repeat on O_2. I am not trying to discredit your tables in any way because, as I say, they are the basis from where we started. They were just not designed for what we need to get out of them.

CAPT THALMANN: But it still goes that if you read the Shields report. The first introduction is

always the apology of listing all of the difficulties and all of the constraints he was put under in publishing that thing.

MR. HOLLAND: Tom Shields has our '84, '85 and '86 records. He has had them already and he can have the lot. We have nothing to hide.

CAPT THALMANN: Not all the companies are willing to go that far.

MR. HOLLAND: I accept that. I do accept that.

CAPT THALMANN: That is the problem. People who are investigating, by and large, if they are really serious about having some input, they are going to have to make their data available in the same format. Not a truckload of dive records. They are going to have to write reports. And they are going to have to write reports like EDU reports where things are broken down. Somebody has analyzed them and has come forward and said, "We have this bends incidence with this schedule," and not try to keep them under wraps. So, that is why the military is not influenced very much by the commercial world, because they do not have the data.

MR. HOLLAND: We try to cooperate with the services. We tried to in a number of areas. I am not going to promise you that we will write reports like the EDU reports because, unfortunately, half the time we are fighting fires. You have people that are better at writing that sort of report.

We put together what we believe is good information. It is true information. We do not like to falsify anything. And we make ourselves look awful at times by putting in accidents. But let us lay the thing on the table. We have problems with supervisors. Supervisors do not run dives as they should. They push them to the limits.

We believe in the 2 plus 2 rule. You would probably criticize us in many cases for being ultracautious when we have a particularly strenuous dive.

All the time, our objective is to keep the DCS rate down. And I think it is appreciated that we have really given the table a fair testing out.

An example. We just did this job where I had this supervisor who can test out anything, who will find whatever is wrong with a procedure, the hard way. Russ Peterson will tell you, we tried the nitrox table out and it works just as well because of some of the things he does with it. We are all forever getting after the guy to pull him back. His enthusiasm is to get the job done. If that enthusiasm keeps going much longer, he would probably go on down the road.

But that particular day, we had just analyzed a bunch of dives on his jobs, and another supervisor was starting to use them--even the surface mixed gas. You know, that really is asking a lot of the table because you are missing out quite a few minutes of the bottom time.

Okay. We did not have too many bends on the job or anything like that, but that is the sort of thing that happens. Unfortunately, in the field; you will say we should control it better. We inspect the jobs. We go out there and we do what we can.

CAPT THALMANN: You can not lay that on the doorstep of table development.

MR. HOLLAND: No, you can not. I am not attempting to.

CAPT THALMANN: Well, part of it. I think you were attempting to.

CHAIRMAN SCHREINER: I would like to comment that it is a distinct pleasure as chairman to have a group of people that is willing to speak without fear or favor openly from their point of view. I would like to congratulate both of you.

DR. LAMBERTSEN: The topic is not the topic of validation. If you look at what is been said, it has to do with development. It is intelligent "random" modification, which is development, and nothing that has been said in this last bit of discussion, excepting the character of the repetitive testing, has had to do with validation.

Dutchy is talking about the evolving tables--not by guess and by God, but by thoughtful injections upon tables. Ed is talking about the validation of a planned table. And what is missing is the validation of the evolved commercial tables.

Nothing has been said about that. No validations, really, that I know of have ever been done on commercial tables in a planned systematic manner.

So, if we just get the topic back to validation, that may help. The particular study that led to this kind of discussion served a great purpose by getting the discussion going. If it does not then lead to self-appraisal and a common approach across industry, non-proprietary, it is not going to do anything.

CAPT HARVEY: There is a frustrating point that I have seen for the last 18-20 years in the Navy. We have the ability to develop, compute, and to a limited laboratory extent, test tables. But many of our tables--particularly, let us say, in the 200-300 foot helium area, that kind of area--after we develop them, the Navy does not have a mission that calls for us diving them very often. We go for extended periods of time without getting the follow-up that would be nice. Investigators turn over and get frustrated because they cannot see a followup.

The commercial people, on the other hand, have a real handicap in not having the research dollars put into developing the tables, but, suddenly, they have got the testing out in the Fleet.

Gentlemen, I suggest that somewhere we need to learn to get together so that the research things that we are able to analyze and compute and put together get to the Fleet. Then we can get the necessary feedback to do some kind of analysis. We need to get together.

MR. HOLLAND: I agree.

MR. IMBERT: I have to put in a excuse for the diving company. We have the will to produce the information. We have the tools, for instance, we (COMEX) have been running a data bank on computers since '74. There is one difficulty, the employee liability. There is no way we can publish company procedure. The only way to do it is when the procedure happens to be official procedure. Like in France, the French Government official tables.

We have the U.S. Navy table which has been used on our work site. We have information, and we cannot release it because of company procedure. The only way to assess the problem is when a government decides to publish information. What has been done by DOE, I think, is excellent because now everyone has information to work with.

CAPT HARVEY: The [U.S.] government has come out within the past year rather strongly about the extension of technology from government research into private industry. It may be that later Dick Garrahan would like to comment on that when he has had time to think about it. Government policy is that we will share and we will make openly available to the commercial industry and other people what we have developed. At least from the government's side, I think there is a policy effort to make these things happen.

DR. BENNETT: I wonder if our commercial friends would like to comment on the validation or the development--you are doing both in a sense--of operational tables with divers on a business job. Do they know they are in fact being used on tables that are not necessarily validated, as it were? You are in a stream of what we get involved within the laboratories, about which we have a lot of concern and for which we are gathered around this table. You are in a sense moving sideways as though it does not apply to you, the kinds of problems we are going to be talking about later, the ethics and all the rest of it, and the legal situations.

MR. HOLLAND: I will ask you one question right back. What is validation? We do not even know. That is the unfortunate thing about it. What we have to do is take all reasonable caution in getting the things in the field, but it will be foolish for us to continue with tables perhaps that were not working as well as they could be when there is something just around the corner we honestly and genuinely know is better. We are not going to put them in the field if they are going to be worse, anyway. But I mean some of them are not always going to be right. At the end of the day, there is nothing which would give us a tool by which we could call a table "validated."

You do not know what validation is; do you, Peter? And I do not. Not really. But we have got some ideas on it.

DR. BENNETT: A point well made. Before this, I was sitting here looking, in fact, and considering what Chris Lambertsen had just said and thinking. "Now, is what I am going to say later really about validation or is it about development?" There is a thin line between the two. But in the end, you develop your tables and then you validate them. And you validate by the frequency and statistical significance of the tables you have developed.

MR. HOLLAND: Until they are validated, they are experimental, technically.

DR. BENNETT: That is the point.

MR. GALERNE: I think we do not do a development as was done 20 years ago. What we do is modify the diving table. We do some improvement. We test new things. So, we are not like 20 years ago, going into the unknown. I would say that mostly what we do now is slightly improve all the time.

Now, to come back to the question of the U.S. Navy and the divers in the commercial field. The problem is that diving tables 10 years ago were still proprietary. They were to improve our competitive position, with the customer. So, the companies were absolutely not responsible to show their tables. They were refusing to do it. They were refusing to give any data. I think now this has disappeared. Any good diving contractor now has a lot of diving tables. We have completed in my company 27,000 different tables. We are up to here, you know. We do not care anymore. It is not proprietary any longer, I am sure Dutchy, has my tables. No? Okay. So, we all know now it is not a professional secret. We all know what the next guy is doing. It is no longer a big economical advantage. So, now, you can expect to see some collaboration.

CHAIRMAN SCHREINER: That is a good input. I appreciate that, too.

VALIDATION OF DECOMPRESSION TABLES;A DIVING DOCTOR'S VIEWPOINT

David A. Youngblood,MD,MPH & TM, Hyperbaric Treatment Center,
University of Hawaii School of Medicine

In twenty years of providing medical support for diving operations, I have had the opportunity to observe the development of decompression tables based upon a variety of mathematical theories. My ineptitude in math has protected me from becoming a disciple of any particular decompression theology and allowed me the freedom to function as an "optimistic agnostic" and remain a relatively unbiased observer. After all, it is we diving doctors who have to face the harsh reality of someone's faulty "fundamental assumption" or the results of premature field release of tables without adequate validation.

Historically our validation of decompression tables has been woefully inadequate. We ignored the statisticians for years, blundering into the field with ten or a dozen "bends free" wetpot dives, expecting success but often finding failure in the open sea. Field modifications followed, almost all of them purely empirical, some based on experience, some based on intuition - and some of them worked. We were lucky. But don't trust luck; trust the statistician. He'll tell you what to expect. Don't leave the laboratory without him.

In the past we have depended upon the reported incidence of decompression sickness as a clinical criterion for the validation of decompression tables. We need a better end point, something sub-clinical i.e. an easily measured alteration in physiology which occurs before clinical decompression sickness and which is reversible. In an engineering sense, we need a method to measure the strain produced by decompression stress before permanent tissue deformation occurs. For instance, in modern cardio-pulmonary stress testing we look for subtle electrophysiological evidence of ischemia long before pain or cardiac muscle damage occurs. Advances in Doppler bubble detection offer great promise for pre-clinical monitoring of decompression stress, but we should search for other complementary devices to measure the stress and strain of decompression before overt sickness occurs.

If we are to extend our scientific measurements into the field - and we certainly should - we must devise a method of accurately monitoring dive profiles as well as dive results. Heretofore we have relied upon written records of questionable validity, but today we have devices which are available to monitor depth and time accurately and record them objectively and even transmit them electronically to a central data bank. We've had good data banks, but we haven't had trustworthy data. The means to accomplish this end is available for the first time; it is only a question of paying the price.

The ultimate validation of decompression tables is quite simple; satisfactory performance in the operational environment. Traditionally this has meant the relative absence of acute effects, i.e. decompression sickness. I maintain that this is shortsighted and inadequate. We must also insist upon the relative absence of chronic effects such as dysbaric osteonecrosis or permanent neurological injury. The history of occupational medicine is replete with examples of work practices, procedures, and toxic exposures which were "generally regarded as safe" until evidence of chronic disease surfaced twenty years later. We have as much responsibility to validate decompression tables for the absence of chronic, long term effects as we do for acute decompression sickness, and we need an international consensus on the medical standards and diagnostic tests required for the prospective studies needed to "rule out" chronic disease or disability associated with particular diving practices.

ADDITIONAL COMMENTS BY DR. YOUNGBLOOD

Tables have to be evaluated, somehow, in the working environment. I think we have a *de facto* process where this is occurring. It was interesting having Claude Harvey describe that salvage job after the airplane at 238 feet or whatever it was. The same observations were made in the Gulf of Mexico around 1969 by people diving the same tables who had just recently left the same Navy; he is absolutely right. They should have reported that back then. And, you know, years later, you make the mistake that they had already found the answer to. That is wrong.

DISCUSSION FOLLOWING DR. YOUNGBLOOD

CAPT THALMANN: One of the things that Dr. Youngblood pointed out is the fact that "generally regarded as safe" is a flexible term and it depends on your experience. When you say "generally safe," it may not be safe tomorrow.

But, by the same token, if magically there appears a set of criteria which could be applied to table development, that would not stop the involvement of generally regarded as safe, simply because now you have some standard to turn to and once it passes it, you are no longer interested in developing it. In other words, it may turn out to be a bit counterproductive.

DR. YOUNGBLOOD: Andre has already answered it, but I can assure you, speaking as a physician who has been involved in the commercial aspect of diving, decompression sickness is not profitable. Companies will continue, if they have problems, to try to improve the tables as long as there are problems. All the empirical improvement that has been done in the last 10 years has mainly been done to reduce the loss of productive work time, from having chambers occupied with treatment recompressions, and to reduce the tremendous expense of DCS-related litigation. So, I do not think progress will stop, because the lack of progress is not profitable.

CAPT THALMANN: To reinforce what you said about laboratory testing being disaster control: I disagree with the idea that you cannot simulate operational conditions in wet pots. You can. The problem arises from a statement which says that a half a percent incidence of bends is unacceptable.

What that means is, if you take a schedule and exactly simulate your operational conditions in the chamber and test it 600 times and have a bend, you still have a reasonable probability of that table generating DCS. So, it may not be that table validations are not properly simulating the conditions, it is just that there are not enough numbers to show that there is going to be a problem. And it is only when it gets out to the field, which is the only place you can test a table, that it then becomes obvious that, "Listen. This is too much. Let's fix it."

Because, when you develop a table, you could simply take a table and say, "Double the decompression time to make them safe." What useful purpose are you going to serve unless you have a reason to do that.

DR. YOUNGBLOOD: I overstated my case by saying it is just a disaster control.

CAPT THALMANN: Well, it is.

DR. YOUNGBLOOD: It is disaster control, but it can be more than that if realistic simulations are practical, but it is not practical to do the number of required tests. But we do have conditions, for instance, in the Middle East, with relatively constant sea conditions and relatively calm waters and which are relatively far away from the plaintiff's bar where significant numbers of dives could be "field tested" to statistical significance.

DR. SHANE: I fully agree with what Dave said about this having to pick a better end-point than pain; but, unfortunately, that is going to require that the basic research be done to determine what is, in fact, the pathophysiology of decompression sickness, which I do not believe we know at the present time.

CAPT HARVEY: I have a little problem with defining what we mean by 0.5%, because I can very easily take all Navy diving, which is a lot,

ships and shallow, and I can have less than 0.5% by a heck of a lot. But if you want me to do it with all my tables between 150 and 200 fsw on air over 30 minutes, I may run into some problems.

The point is, your less than 0.5% applies where you are doing your diving, and that may be a broad spectrum one year and a narrow spectrum the next, and it will be slanted heavily by the jobs you get. I am not sure that picking a magic number is necessarily the correct way to approach this thing.

CHAIRMAN SCHREINER: I think the magic number of Mr. Holland is zero.

LCDR HOBSON: Also, there is one point further to this, that the less than 0.5% that you would like to have is field experience. Now, in the lab that should be your worst case scenario. By the time you get finished, if you achieve a 1% in the lab, you can virtually guarantee that once they get out to the field that that rate is going to drop. So, I think 0.5% is very, very extreme for a lab scenario. For an operational field evaluation after years and years and years, I would see that as being quite acceptable.

DR. LAMBERTSEN: The percentages you are talking about are incidence of a problem in people using an exposure. If the exposure was just fine in the lab, in the field people are not all just fine. So, what you are dealing with is two separate matters of statistics: The shape of the population, and extremes. You may be coming up against an absolute brick wall here if you ignore the fact that somebody is going to foul up every run, lab or outside.

CANADA'S APPROACH TO DECOMPRESSION TABLES

Jan Merta
Canadian Oil and Gas Lands Administration

My department, the Canadian Oil and Gas Lands Administration (COGLA) is jointly responsible to the Department of Mines and Resources and the Bureau of Indian Affairs. We are responsible for safety of diving operation in Canadian Federal waters. I would like to tell you how we view the matter of validation of tables, and how I try to implement this policy.

When I started in the position of Chief Inspector of Diving six years ago there was very little information about validation or recording of diving activity or the DCS incidence in Canada. The companies more or less kept everything close to their chests, and it was difficult to determine how good their diving operations were or what their DCS incidences were for normal working dives.

Therefore, from the outset my department began to require the Operator--which is usually the oil company--to submit a proposal for what they wanted to do. If the proposal called for a diving program, then we required whatever we felt was necessary to evaluate a program. This was not from the diving contractor, but from the oil company operator, who then chooses a diving contractor he feels might meet the requirements. If there is a problem, I usually deal with the Operator, again, rather than with the diving contractor. Thus I deal both with the diving contractors and oil operators.

Before the permit to dive is granted, usually we require any diving contractor who has not dealt with us before to submit a complete set of decompression tables, procedures, operations manuals, administrative documents, other information including emergency scenarios, and other things we feel are needed.

I usually invite the company representative, either the senior manager or chief supervisor, to have a session with me and go over all the problems which might be relevant to the safety of their diving operation.

We scrutinize very carefully, for example, the typical decompression schedule they will be using, for the diving depths where they will be working.

When we fully understand each other and the diving table submitted seems to be sound so far, based on the past track record because that may be the only evidence we have to go on, then we will give agreement for use of the tables as submitted. That means anything that is written in instructions, in the manuals and all, is approved as it was agreed upon. From there on, we do not allow any change to any procedure without discussion and approval from my department. This way we try to prevent changes which might later on turn out to be a problem.

In order to build a track record of the diving activities in Canada and to be able to establish a sound base which can used for evaluation of existing decompression tables and development of new ones, about five years ago we began a dialogue with the diving industry in Canada. We explained to them the predicament we were in of lacking a sound base on which future judgments could be made. A man's judgment is only as good as the information he has, and we had very little. So, we decided with the cooperation of the diving contractor that we might build such a base in Canada. This is being done with the help of the Canadian Association of Diving Contractors (CADC). They are an integral part, because COGLA's jurisdiction only deals with diving activities from twelve miles to 200 miles of shore. Other diving activities are under Provincial jurisdiction, and we would lose that vital set of data if we had not worked out a scheme with CADC.

We have initiated a divers' data base, which has been working for the last three years. It is a comprehensive data base covering individual Canadian offshore divers. Simultaneously with the divers' data base, we have developed a standard dive log book for divers, and also a report sheet for the companies' diving activities under our jurisdiction. Some diving activities in Canada also use it. This meets the criteria for privacy, and because of that we have to keep it confidential.

These report sheets were filled in regularly, and our office was getting from every diving opera-

tion, on a daily basis, a Telex of the results of any diving activities going on. This meant I knew whether they were diving or not and things like the depths and the names of the divers. We entered all of this information into our computer with the bottom time, type of work, guidelines they used, and whether there was an incident during the dive.

Having this information for a reasonable time, I started to see some interesting things which might not necessarily be relevant to the tables. That is, the DCS incidence of a table might not be caused by the table, but by the way the table was used.

As an example, I noticed three divers who were treated for a slight pain-only type problem. When I looked through my data base, I discovered that every time it happened one particular supervisor was running the dive. Going to the supervisor, I was able to find that he was not using the tables properly. After talking to him and suggesting some changes, we have had no further reports of similar problems.

As a result of the information being gathered and the guidelines we have established in keeping close track of what dives are being done and what are their outcomes, every incident is being reported and scrutinized. We have established an education process in Canada, having regular yearly seminars for diving personnel at the University of Newfoundland and in Toronto, and an annual CADC conference. In general, we have been able to get good overall understanding and concern. Since the end of 1983 I have not had any report of any diving incident which was related to the decompression tables, irrespective of which tables were in use. That includes U.S. Navy tables. We do all kinds of diving, from very shallow to rather deep for air tables.

Based on what we have learned for this particular information, and in order to understand better what it means to validate tables and approve the ones that are sound, and to sort out the others which are a little bit uncertain, I have initiated a new study with the Canadian Association of Diving Contractors. Dr. Bill Hamilton is the principal investigator. This study focuses exactly on what Dutchy Holland was mentioning. It will be a data base for storing dive records, profiles, etc. We plan to include diving records made available to us by the diving industry. The records will be entered from company dive logs into a computer for storage and analysis. Hopefully, we will be able to analyze from this data different types of tables, how much has been done using specific tables, average depths, DCS incidence rates, etc.

The U.K. Department of Energy has already authorized, for example, DCIEM air tables, but I have not yet done so because I do not know the track record. Certainly I have nothing against these tables. In view of the track record of existing tables used in Canada, it is hard for me to simply say that their tables will be as good. It appears that their experimental incident ratio is far greater than what we have been seeing in the field for the last four years.

Offshore diving is quiet right now, but there is quite a bit of diving going on inland using these tables; the study will look very carefully at hundreds of dives done with the DCIEM tables, and compare them against other data we gathered from the diving industry. Then I will make a decision as to the validity of these tables.

So, I feel that from this point of view, we in Canada are trying to keep some objectivity. I am trying to go about it empirically because that is the first step. Perhaps later on, we will eventually have a very large and comprehensive data base. We hope to develop some standard report sheet which will allow us to keep uniform records and then in some way develop the methodology to compare and evaluate new tables.

I personally believe very much in progress, and that one should never stop and decide that since we have no problem with these tables there is no need to work on new ones. I feel that new tables might increase our bottom times, perhaps will be shorter, and should be equally as safe. But my primary responsibility is for the diver. Before I let some tables be used which do not have a record in the field, irrespective of how well they have been developed and validated in the lab, I will err on the side of caution and will require some further examination as they are put to use in the field. This will then be matched against the data base I hope to have in place.

From this study they expect to put in as many as 25,000 dives. We will be able to do analyses much like those of Dr. Shields in England. We

will be able to take a much closer look at the data and see whether we can extrapolate some further information.

But for the present I feel that table evaluation, in order to be reliable, has to first ensure that the tables are used as they should be in the field, that there are no deviations, and that one has maximum control over the procedures and other techniques which might affect the outcome of a particular table.

So, we have taken other steps and have developed in Canada "EARS," Emergency Automatic Recording System. Our office has supported the development of this unit at the level of about $150,000. The unit basically is a black box for the diving industry, which now, under Canadian regulations, is required on all deep diving systems--diving bells and decompression chambers with human occupancy. This system is now presently at DCIEM undergoing extensive tests and evaluations. It has been used for a year by the Underwater Training Center in Toronto. The unit is fully sealed, pressure resistant, and capable of taking 16 channels simultaneously. We can record the time, depth, pressure inside the bell, outside water temperature, partial pressure of oxygen, the diver's depth, etc.

All that is tamper-proof, so we can retrieve it anytime for investigation, and can record the output in a supervisor's shack, straight, so he can have a copy of his log exactly as it happens. So, with this type of information I am hoping that we will be able to gather reliable data and, as time goes, will have some base which will make evaluation of tables more and more objective. But at present I am looking at each table individually. I am looking at the track record behind the table: How long has it been used, what is the typical use of that table, how many problems have been experienced with that table, who developed the table, does the company understand the table, how does the company want to use the table, and who will be the people who will be using the table.

Because we have good control of who is working in our Canadian offshore, we can not only encourage better training in the use of tables through the training schools, but we are working to get better interpretation, for example, of decompression sickness. It is a mandatory requirement that every diver has minimum amount of emergency medical training, including a module concerning hyperbarics, and at least one member of the crew on any installation has advanced hyperbaric training. I believe that their interpretation of decompression problems or any symptoms is getting to be pretty well what we understand it to be.

Now, I know that there are problems for a company to report, sometimes, an incident which they successfully handled. But as I said, I trust the industry, because we agree that we want to find the problems and have the best safety record because everybody will benefit: this will eventually improve the insurance rate.That's the story in Canada.

DISCUSSION FOLLOWING DR. MERTA

CAPT HARVEY: One of the difficulties of comparing tables for their validity is that there seems to be no consistent agreement on how we sub-divide these tables into little blocks, or groups. If UHMS or someone could come out with a suggested guideline for our reports and analyses, it might be very useful to everyone concerned. I find it difficult to cross-compare tables or sets of tables with maybe one bad in the deeper end and one bad in the shallow end, or what have you. I would like some arbitrary blocks that we can agree on.

CHAIRMAN SCHREINER: That is a good suggestion. Dr. Merta, let me ask you a question: When you issue a diving permit after duly scrutinizing the procedures and the capabilities of the diving contractor, do you thereby relieve the diving contractor for responsibility for proving that his procedure is appropriate? Is that tantamount to a government endorsement of the procedure in Canada?

DR. MERTA: We do approve every operation, including the diving. It is not that we in some way are taking responsibility from the contractor. What we are saying is that what they have presented to us is acceptable to us from the point of view of sound diving technique, for example, or training, medical treatments, et cetera. Now, the situation might change during the operation. We

have a set of regulations. As long as they follow regulations and everything is sort of as it should, then if something happens, obviously, we investigate.

Obviously, we do not act as a certifying authority which will put a stamp of approval on the table. We just scrutinize things, trying to assure that they meet minimum safety criteria. A contractor can improve and go further.

CAPT THALMANN: Did I understand that in your investigation of diving incidents, you did not find any decompression sickness which is directly attributable to the table?

DR. MERTA: Yes.

CAPT THALMANN: It was attributed to how the table was used?

DR. MERTA: Yes.

CAPT THALMANN: I think somebody ought to underline that in capital letters. Let me ask Dutchy Holland the second question. If you have supervisors who are screwing up your tables, why do not you fire them?

MR. HOLLAND: We do.

CAPT THALMANN: Good.

CHAIRMAN SCHREINER: I tell you this is not easy; it shows that much comes out in the discussion that would never come out in the formal presentation.

LEGAL ASPECTS OF DECOMPRESSION TABLE VALIDATION

James R. Sutterfield
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An Overview of the Need for Diving Table Validation Vis-a-Vis Legal Liabilities

Commercial oilfield divers who work for one diving company on a permanent basis and are who assigned to a particular vessel regularly used to transport the divers to their locations may be considered seamen and have the protection and remedies provided by a federal statute called the Jones Act[1]. If injured, these divers can sue their employer and can recover damages if there is any negligence, even in the slightest degree, which was a cause of their injury[2]. They have a right to bring suit in federal or state courts[3] and can demand a trial by jury[4].

Divers who freelance for several companies, or those who have a principal employer but are associated with different vessels, may or may not be considered seamen depending on the facts and circumstances of their relationship to the company and to the vessel[5]. The trend of the courts seems to be away from finding non-traditional seamen, such as commercial oilfield divers, to be Jones Act seamen[6]. However, if they are not considered seamen but simply maritime workers, an injured diver is not without remedy against his employer. As a seaman, an injured diver is owed maintenance and cure, that is, medical treatment and reimbursement for the value of room and board which he would have had aboard ship, save for his injury[7]. This is without regard to his employer's negligence. As a non-seaman maritime worker, he is entitled to medical attention and weekly compensation.

The diver can also sue the owner of the vessel on which he was employed. This claim is asserted against the vessel owner whether or not the owner is the diver's employer[8].

If the diver is not working from a vessel but rather from a fixed structure, he will not be considered a seaman. If the fixed structure is a platform on the Outer Continental Shelf, he may be entitled to a remedy for compensation under the Longshore and Harbor Workers Compensation Act[9]. If the fixed platform is located within the territorial waters of a state, he may be limited to benefits under the compensation laws of that particular state[10]. If the diver is killed while working from a vessel more than three nautical miles from the boundary of a state, he is entitled to remedies under the Death on the High Seas Act, without regard to his status as a seaman[11].

With respect to decompression tables, there are practically no reported court decisions which deal with validation or where there has been a determination of the validity of the use of any particular table. Thus, my knowledge on this subject comes from practical experience in handling diving cases during my 20 years of practice, and discussions which I have had with other maritime law practitioners and expert witnesses, both on the plaintiff and defense side of the bar. Most of the cases involving injured divers where the validity or use of decompression tables comes into question are settled before or during trial. Often the reason for settling is the lack of sophistication of the trier of fact (whether judge or jury) and the general sentiment that the American tort system has moved away from being fault-based and is now based more on social considerations.[12]

Unfortunately, too often the practice in the commercial oilfield industry has been to use decompression tables that have not been validated by the user. In most cases, the tables were "borrowed" from the U.S. Navy or one of the older diving companies and then modified through the use of computer simulation techniques to utilize the table at depths greater than those for which originally designed. Thus, counsel for an injured diver can easily argue that the commercial oilfield diver has become a guinea pig for these "new" tables.

Even if the tables are successfully used over a period of time, the judge or jury may still conclude that the tables were inadequate to prevent the particular injury involved in the lawsuit at hand. Often, review of the dive logs proves that the tables were not followed to the letter. The plaintiff's attorney then has an easy job of showing negligence of the diving company and its supervisory personnel. To use a worn phrase, it is a "Catch 22" situation. If the tables were not followed, therein lies the employer's negligence. If the tables were followed to perfection, the fact that the diver was injured proves that the tables were flawed. Even in those

few situations where it can be proven that the diver intentionally disregarded safe practices, the employer will still bear a share of responsibility (and legal liability) as the seaman's duty to protect himself is slight.[13]

When the dangers inherent in commercial oilfield diving and the divers' compensation are explained to a jury, they often recognize that this is a high risk occupation and conclude that the diver bears considerable responsibility for his own health and safety. Although the diver cannot be blamed for selection of the decompression table, if he fails to follow directions during the decompression process or refuses to return for recompression when he has symptoms of the bends, juries may often assess the diver with a sizable percentage of contributory negligence. Under the general maritime law, comparative negligence applies and the percentage of negligence of the diver will reduce his judgment correspondingly.

Diving companies have had the greatest success in defending against claims when they have followed the U.S. Navy diving procedures and the Navy tables. However, following a government standard is no guarantee that an employer will be exonerated from responsibility. In some cases, plaintiff's counsel have effectively convinced the trier of fact that the Navy tables were designed primarily for inspection dives and not for the strenuous exercise required in commercial oilfield diving operations.

From a practical standpoint, until there has been validation of decompression tables for diving at depths greater than those allowed by the U. S. Navy tables, diving companies will continue to find it difficult to win lawsuits brought by injured divers.

Legal Aspects of Validation Testing

The attempt to establish, through simulation and then by actual field testing, a series of tables approved by an official agency of the United States government for use in commercial oilfield diving operations is, itself, not without legal pitfalls.

Testing, in order to be effective, must ultimately involve human test subjects. Several years ago, the F. G. Hall Laboratory at Duke University conducted a series of simulated deep dive experiments called the Atlantis Series, under the direction of Dr. Peter Bennett, the director of the Laboratory. The purpose of these dives was to research high pressure nervous syndrome. Only experienced divers were employed as experimental subjects. Despite extensive predive testing and work-up, and despite the fact that he had participated in the first series of dives with no ill effects, one of the testing subjects suffered permanent organic brain damage which was attributed by him to the effects of his participation in the Atlantis III dive which went to a simulated depth of 2,250 feet as planned, setting a new world record. It should come as a shock to no one familiar with our litigious society that this subject filed suit. I am pleased to say that the court in that case dismissed the suit and, in so doing, not only vindicated the actions of Duke and its representatives, but saved the day for testing with use of human experimental subjects by setting forth, in effect, a set of guidelines for this participation.[14]

The lawsuit primarily centered around claims that the researchers failed to disclose certain dangers inherent within the testing and, alternatively, that the testing was an ultrahazardous activity subject to laws of strict liability.[15] To deal with the latter first, the court felt that the type of research being conducted under the conditions present was not such an ultrahazardous activity as to justify the application of the doctrine of strict liability. Concerning the claim of failure to disclose certain dangers, the court explored at length the factors involved in valid, informed consent.

Non-therapeutic experimentation is defined as that experimentation not directed toward providing a benefit to the subject, but instead concerned with the discovery of data through the research on that subject. The issue of informed consent will often be controlled by case law or statutory law of the state wherein the testing is taking place. In order to properly present a case based upon failure to disclose, a test subject must show that the persons conducting the experiments made a representation relating to a material fact either past or existing; that the representation was false; that the experimenters knew the representation was false when it was made or made it recklessly without any knowledge of its truth and as a positive assertion; that the experimenters made the false representation with the intention that it should be relied upon by the test subject; that the test subject reasonably relied upon the representation and acted upon it; and, finally,

that the subject suffered injuries as a result thereof. The Atlantis Series case turned upon the fact that the subject admitted that he knew the possibility of organic brain damage existed whenever compression and decompression were involved if not properly treated, as well as the fact that the scientists conducting the experiment were unaware of this condition being a normal condition for experimental deep diving. In fact, the scientist indicated that if, in fact, the subject had sustained the type of damage alleged, it would be the first case ever. Further, all risks pertaining to deep diving that had occurred in the past were included on the informed consent form.

As stated, the Atlantis Series case provides a comprehensive guideline for conducting simulated testing. As simulated testing does not take place actually in the water, no maritime law aspects are involved and the legal aspects will be controlled by land-based law, usually that of the state wherein the testing is involved, as supplemented by overriding federal legal considerations. The legal aspects of simulated testing for table validation would be exactly the same as any testing involving human subjects.

To the extent that field testing in actual water depths would be required for validation of tables, there are other sets of laws with which one must be concerned. The first is the knowledge that if an agency of the United States Government, such as NOAA is conducting these tests by employing either testing subjects itself or contracting with others to do so, it has legal exposure by virtue of the Federal Tort Claims Act which subjects the United States to liability for the torts of its employees in the same manner and to the same extent as private individuals would be liable under similar circumstances.[16]

In theory, such field testing could be conducted by scientific personnel diving from vessels regulated by the terms of the Oceanographic Research Vessels Act (ORVA).[17] I say theoretically because an exhaustive search has not turned up one case involving a claim brought by a diver conducting any sort of diving test. However, the act exempts vessels which the Secretary of the Department of Transportation has certified[18] to be a vessel employed, among other things, "exclusively in oceanographic research, including, but not limited to, such studies pertaining to the sea as seismic, gravity, meter and magnetic exploration and other marine geophysical or geological surveys, atmospheric research and biological research."[19] The Act further defines "scientific personnel" as persons aboard a vessel solely for the purpose of engaging in scientific research, etc.[20] and specifically excludes from the category persons aboard who are involved in the navigation of the vessel.[21] The importance of the Act is that the scientific personnel aboard an oceanographic research vessel are not considered seaman for the purposes of the Jones Act. By case law, they have been extended the benefits of the warranty of seaworthiness,[22] i.e. the vessel owner owes them a duty of making sure that the vessel is fit for its intended purpose, but they have no right to sue their employer under the Jones Act. Any claim they would have against their employer other than as the vessel owner, would be addressed under the Longshore and Harbor Workers Compensation Act and they would be relegated to compensation and medical expenses.

FOOTNOTES

1. 46 U.S.C. 688, et. seq.; Barrett v. Chevron, Inc., 781 F.2d 767 (5th Cir. 1986); Pickle v. International Oilfield Divers, Inc., 791 F.2d 1237 (5th Cir. 1986); and Wallace v. Oceaneering Inter- national, 727 F.2d 427 (5th Cir. 1984).
2. Rogers v. Missouri Pacific Railroad Company, 352 U.S. 500, 77 S.Ct. 443, 1 L.Ed.2d 493 (1957); Spinks v. Chevron Oil Company, 507 F.2d 216 (5th Cir. 1975); Ferguson v. Moore-McCormack Lines, Inc., 352 U.S. 521, 77 S.Ct. 457, 1 L.Ed.2d 511 (1957).
3. United States Constitution, Article 3, Section 2; Southern Pacific Company v. Jenson, 244 U.S. 205, 37 S.Ct. 524, 61 L.Ed. 1086 (1917); Engel v. Davenport, 271 U.S. 33, 46 S.Ct. 410, 1926 AMC 679 (1926); Panama R. Company v. Vasquez, 271 U.S. 557, 46 S.Ct. 596, 1926 AMC 984 (1926).
4. Under the Jones Act, the plaintiff's claim may be brought either on the "law side" or on the "admiralty side" of the court. If brought on the admiralty side, the claim is tried by a judge and the claimant is usually granted interest from the date of injury. If brought on the law side, the claimant is entitled to have the case heard by a jury but interest accrues only from the date of judgment.
5. Barrett, supra; Pickle, supra; and Wallace, supra.
6. Johnson v. John F. Beasly Construction Company, 742 F.2d 1054, (7th Cir. 1984).

7. Farrell v. United States, 336 U.S. 511, 69 S.Ct. 7097, 93 L.Ed 850 (1949); Mahramas v. American Export Isbrandtsen Lines, Inc., 475 F.2d 165 (2nd Cir. 1975).
8. A seaman has a claim under the general maritime law against the vessel owner for the unseaworthiness of the vessel. Complaint of Merry Shipping, Inc., 650 F.2d 622 (5th Cir. 1981); Landry v. Oceanic Contractors, Inc., 731 F.2d 299 (5th Cir. 1984). A "maritime employee" (i.e. non-seaman) has a claim against the vessel owner under 33 U.S.C. 905(b).
9. Longshore and Harbor Workers Compensation Act; 33 U.S.C. Sec. 901, et. seq.
10. Outer Continental Shelf Lands Act, 43 U.S.C. Sec. 1333 (B); Herb's Welding v. Gray, 703 F.2d 176 (5th Cir. 1983); 105 S.Ct. 1421 (1985), on remand 776 F.2d 898 (5th Cir. 1986).
11. 46 U.S.C. Sec. 761, et. seq. Under the Death on the High Seas Act (DOHSA), the representatives of a deceased seaman are only entitled to recover pecuniary losses. Under the Jones Act, which applies in death situations within the three nautical miles, damages may also be awarded for non-pecuniary losses such as love and affection.
12. Tort reform, in response to the much publicized "insurance crisis" is a hotly-debated issue on the state and national level, and is beyond the scope of this paper.
13. Wyatt v. Penrod Drilling Co., 735 F.2d 951 (5th Cir. 1984); Leja v. Mike Hooks, Inc., 690 F.2d 10 (5th Cir. 1982).
14. Whitelock v. Duke University, 637 F.Supp. 1463 (M.D.N.C. 1986).
15. Certain activities, such as mining and pile driving, are considered by the courts to be ultrahazardous. The defendant company can be found to be "strictly liable" to the injured party upon a showing of a causal connection between the activity and injury. The plaintiff is not required to prove negligence on behalf of the defendant.
16. 28 U.S.C. 1346(b).
17. 46 U.S.C. 441-445.
18. In a case handled by the author's law firm, Smith v. Odom Offshore Surveys, Inc., 791 F.2d 441 (5th Cir. 1986), the Court of Appeals for the Fifth Circuit held that in order for a vessel to be deemed to be an "oceanographic research vessel," it must be designated as such by the Secretary of the department in which the Coast Guard is operatng. Id at 413-414.
19. 46 U.S.C. 441-445.
20. 46 U.S.C. 441.
21. Craig v. M/V PEACOCK, 760 F.2d 953 (9th Cir. 1983)
22. Id.

ADDITIONAL COMMENTS BY MR. SUTTERFIELD

If anyone does not know, the Jones Act is a statute of the United States enacted in about 1920 for the benefit of seamen. It requires a more or less permanent attachment to a vessel. The employee has to be--had to be--an employee of the vessel and he had to contribute to the mission of the vessel. When the exploration of the Gulf of Mexico occurred, suddenly, there were some people who used to be known as welders and oil field roustabouts who suddenly said, "Hey, I'm a seaman because I'm out here working, suffering the problems of the sea." And some of the courts agreed with them.

One other thing about the Jones Act. The only real requirement is that a suit under the Jones Act be brought in the district wherein there is a navigable stream. So, you can have a lot of cases filed in Beaumont, Texas, for example, because there are some judges in that district that seem to have a different view of what the law should be than a lot of us. Plaintiff's tend to find these judges.

But it works both ways. The 7th Circuit has taken what I believe to be a much more realistic attitude of what the Congress meant when they passed the Jones Act. In the 7th Circuit, a person aboard a vessel has to be there to aid in the navigation of the vessel in order to be considered a seaman.

It is also very important to know one reason why all the plaintiff lawyers try to make the people seaman. That is that they really do not make much of a fee if he is considered a longshoreman, because then he gets a set schedule and there is usually not even a reason to file a lawsuit. If he is able to make his client a Jones Act seaman, he gets somewhere from 25 to 40% of the award.

And there is another thing in the law, it is called, "You take your victim as you find him." Certain people are more susceptible to any sort of injury than others. That has to be taken into consideration as well.

Given those few situations where it can be proven that the diver intentionally disregard safe practices, the employer will still bear a share of the responsibility and legal liability as a seaman's duty to protect himself is slight. Slight, it is almost nonexistent. It is existent, but it is extremely slight.

So make sure if you are planning to take advantage of ORVA that you have your legal department go down to the Coast Guard and get your vessel certified.

DISCUSSION FOLLOWING MR. SUTTERFIELD

DR. YOUNGBLOOD: I just want to make sure that everybody heard you on that principal about, "you take them as found." That is something I find, in reviewing diving cases, that diving companies often do not comprehend.

MR. SUTTERFIELD: I do not think that we could overly stress the importance of a good pre-employment physical for any divers, or pre-dive physicals to make sure that the guy that you are sending out is physically capable of doing the work. If you do send anyone out that is not, you are going to pay for it.

DR. YOUNGBLOOD: A particular area where it is expensive to look is the organic brain disease situation, because that is the one that is really expensive if the claim is brought against you.

MR. GALERNE: Do you think we could scare the divers if we look at their brain?

DR. YOUNGBLOOD: Well, you jest, Andre, but that is usually what the unsophisticated diving contractor says. If you look and there is damage, you can either not employ him or you know it is there and if anything happens, "it comes out in the wash."

MR. GALERNE: It was a joke.

DR. YOUNGBLOOD: Oh, I know it is with you. It is not with some of your friends, though.

MR. SUTTERFIELD: Let me make one comment about something that was brought up earlier about waivers. It is against public policy to allow someone to waive a negligence claim against another party before it has occurred. In effect,

you can not give anyone a free shot. These waivers do not work.

You can inform them of all the bad things that could possibly happen to them, and if one of those things happens by virtue of something other than negligence, that is fine. They have understood that; but you cannot absolve yourself from negligence simply by getting someone to sign a waiver. It is against public policy.

CHAIRMAN SCHREINER: Let me ask you a question about the jury trials that a seaman can request under the Jones Act. That is a civil jury, I take it.

MR. SUTTERFIELD: In Federal court, it is a jury of six. Some states allow a jury of twelve.

CHAIRMAN SCHREINER: But the decisions are made by majority vote.

MR. SUTTERFIELD: Yes.

CHAIRMAN SCHREINER: You do not need unanimity as in a criminal jury, do you?

MR. SUTTERFIELD: Well, it depends. Within the Federal system, you do not. But it depends upon the jurisdiction. That is a local matter. Some states require the unanimous verdict. They generally all agree to the verdict.

MR. HOLLAND: There may be something happening in the UK which could give all of us guys with organic brain disease some hope. The University of Lancaster is attempting at the moment to prove that all divers after a time, as they get older, suffer from, I do not know the technical word, organic brain disease, I guess.

DR. SCHANE: I have two things that relate to that. The first is that Peter Norris is the guy at Lancaster who is doing that work. Also, a former student of Dr. Lambertsen by the name of Joe Idicula reported in 1982 at the Naval Symposium in Bombay that CT scans of veteran divers showed similar effects of those of punch drunk boxers.

DR. ELLIOTT: We are talking about an endpoint which is related to decompression validation, but, obviously, since rather like other things such as benzene and leukemia, with a 10-15 year lead time, you can not pin the particular dive down. So, it is really not in our consideration today. But, at the same time, one is very concerned about this. What is happening in the UK that I think is relevant is the Medical Research Council's Decompression Sickness Panel has now got a working group on long-term health effects in order to assess the evidence for the alleged long-term effects on every organ system, including the central nervous system, with the intention of producing a review within the next year or two.

Now, I do not think we are unique in this, but I think the track record of the MRC Panel is such that it should be reasonably authoritative, and as some of you know, we are actually having a workshop in the spring of 1987 on diagnostic procedures in decompression neurology.

MR. SUTTERFIELD: Two quick things I made a note of in chatting with people earlier. Someone talked about what we have called the state-of-the-art defense, and that is at the time such-and-such occurred. You did everything that was known in scientific circles about this situation, but then later the knowledge has increased. We now know that, for example, that asbestosis matters; others are diethylstilbestrol, silicosis, etc. At the time those things were not thought to be harmful, and then later we find out that they are.

State-of-the-art defenses do exist. You say, "Well, at the time we did everything totally proper." However, state-of-the-art defenses generally do not succeed, in my experience, when you are talking about people. If you are talking about property damage, yes. You win on those all the time. When you are talking about people, they generally find a way to get around the state-of-the-art defense simply because they just feel because of social values that the people should be taken care of. And that is what we have had in asbestosis and diethylstilbestrol. It is something that could happen in the diving industry with organic brain damage, etc. You say, "Well, we did not know that then but now we know it." Unfortunately, you may have to pay for it.

The other thing is that if, in fact, the Federal Government were to establish certain tables and guidelines and if you followed those, you should

be okay. The Federal Government could get into that business and could promulgate diving tables, and then the Congress could pass some sort of National Tort Act that said that, "If, in fact, you follow these tables, then you will not be considered liable," etc. It is possible. They have done that in certain cases, like with hospitals on a state level. They have said, "You are not going to be responsible for selling blood, as long as you follow certain guidelines." When that has happened it has been necessary in order to get people to be in that business. If diving ever becomes such a necessity that they feel it is worth it and that is the only way they can do it, something like that may happen. But until then, I would not hold out a lot of hope for it.

DR. YOUNGBLOOD: There is a real problem there, which I think Jan Merta or somebody alluded to earlier which we saw happen in the tunneling industry in the matter of long term effects. Unless we consider the implications that are possible with long term effects, if we should go the short term route of validating on the basis of acute criteria only, we could get into the situation of the tunnel industry. In certain states, certain schedules were mandatory. You could not do anything else. Then we discovered that the long-term effects were there, but the contractors were almost legally bound.

MR. SUTTERFIELD: My knowledge of OSHA is somewhat limited. It is my recollection that it provides that nothing in the Act itself should affect the civil liabilities of the employer. What they try to do is make sure that no one could either sue on behalf of OSHA, per se, or defend on that basis. If what you have said is correct, it is something that has to be addressed by trying to get the regulation changed or trying to get the tables changed.

DR. YOUNGBLOOD: What it leads to is aseptic bone necrosis. I was not considering it from the litigation standpoint. The point is that it cements things at that point and closes the mind against either the possibility of long-term damage or the possibility of further improvement in the procedures.

MR. SUTTERFIELD: If it is something that you are required absolutely to do just one way, then I do not really know. But if it is a regulation that it is a minimal standard--I think most OSHA regulations are minimum standards--and just because you meet that minimum standard, if you, as an expert in that field, know that you should do more than that, then you have to do that. You are not going to be shielded from civil liability simply by following the OSHA minimum standard.

MR. HADDON: Several years back under the Eula Bingham administration, there was a program directive written that said you could use a consensus standard that is better than OSHA standard if you were aware that it was better; that was permissible. At first it said it would be a d-minus charge, and then they eliminated that. And, so, OSHA does recognize that things change. There can be improved conditions.

A DEVELOPER'S VIEW OF NEW DECOMPRESSION PROCEDURES

R.W. Hamilton
Hamilton Research Ltd.

Introduction

This is a "position paper" from one who has over the last couple of decades been involved in or watched closely the development and introduction of a number of new decompression tables and procedures in a variety of environments. I can report both successful and some not-so-successful experiences. These have led me to a general concept of how, in my opinion, the "final" steps in the process of decompression procedure development might safely, effectively, and ethically be carried out. Let me first summarize the concept, then state my premises, lay out a working plan in more detail, and tell a story or two. The idea is simple and straightforward, but it may require some judgement at several points in order to be implemented.

New procedures are given appropriate "testing" under "laboratory conditions," and are then introduced into "provisional" operational use under controlled conditions. This calls for their being used by competent crews and divers under expert supervision, at sites where prompt and adequate treatment capability is readily available, and with careful and valid records keeping. Results are fed back, modifications made where necessary, and when sufficient experience in their use has been accumulated the provisional tables can be declared operational. However, decompression tables should never properly be regarded as "finished," but should be susceptible to revision whenever it makes sense.

Background

The first and foremost premise behind this approach is well known to all of this group but has to be mentioned, that successful new decompression procedures are based on decompression experience. Various mathematical, graphical, intuitive, and other processes are used to translate previous experience into new procedures. One might be tempted to say at this point that a set of new procedures--given the set of transition processes currently available--are no better than the experience on which they are based. That is not strictly true, because we learn from experience, and in any evolutionary design process whether it be the engine for a car or the recipe for a cake, we try to strengthen the weak points of the previous versions in the next edition. A second premise says that where proper capability to treat DCS is in place there should be no significantly greater risk *as a result of decompression sickness* to the diver in the field than to the one in the laboratory. Other field-related risks will certainly be greater there than in the lab, but these are not particularly related to the reliability of the decompression table. When recognized early and treated promptly, the DCS (decompression sickness) that might ensue from the unreliability of a decompression procedure poses little threat of lasting injury. The cases where "decompression sickness" has caused injury have virtually all been the result of delayed, improper, or inadequate treatment, or of some factor other than DCS (such as blowup and/or embolism).

Other factors have been brought out earlier in this meeting. Even an immense "laboratory" program may fail to establish a table's true reliability for its use under field conditions. Further, laboratory programs nowadays may be seriously constrained by ethical or insurance considerations, not to mention the costs. Because DCS occurs as a probabilistic or statistical event, the practicality of definitive laboratory testing, even with adjuncts such as bubble detection, will diminish as experience and hence reliability improve; it takes a lot more dives to establish that a DCS incidence is less than say 0.1% than to see an incidence when it is 10% or more.

While DCS may be inevitable, it should never be regarded as acceptable.

No practical diving procedures can be guaranteed to be totally free of DCS. The reliability of a set of decompression tables is a series of shades of gray, not areas of black and white.

Proposed plan for table validation

Here is a suggested "general" plan for validating a new set of decompression tables. It is neither complete nor definitive, but it covers the basic ideas; the main theme is to proceed with careful *small steps*. Figure 1 shows this diagrammatically.

Plan the validation

To begin with, the source of the new tables should be considered when planning the validation. If they closely resemble other tables whose reliability has been established, one would require few if any chamber tests before starting provisional field use. On the other hand, if the new procedures are based on novel concepts or fall in a category where there is little experience, a more extensive laboratory testing package or even a development program should be performed before considering serious field use. Validation would be performed on the product of the development program.

How many chamber tests?

This is an area where some judgement has to be applied. The choice of how many and what kind of tests to perform depends on how closely linked the new procedures are to valid experience, and also on how reliable and how relevant that experience was. And how well the new tables work.

It should be recognized that these chamber or laboratory validation tests are not intended to establish a "bends incidence" but rather to expose any catastrophic malfunctions in the development process. It is certainly unrealistic to expect that a series of chamber dives will prove that a set of tables will not result in DCS. They represent some small steps.

Before any great efforts are spent in validation it would be advisable to have procedures that are relatively new looked at by someone other than the table designers, preferably by someone experienced in and involved in the operational use for which the new tables are intended. This is not so much to try to predict the decompression reliability but to see if the patterns look reasonable, and to check that operational details such as gas switches are manageable and will be accepted by the divers.

Provisional use at sea

In general terms I would consider it all right to go directly to sea use under controlled conditions (discussed later) when the "new" tables in question are closely related to established experience and when the changes are designed to be in a conservative direction. This could be compared to the common practice of jumping to a deeper or longer table to add conservatism when the supervisor determines that it is needed. Small steps.

A half dozen or so validation dives might be needed for a less conventional modification such as speeding up decompression by increasing the level of oxygen breathed by the diver.

For a virtually new process such as diving with exotic gas mixtures or use of a constant PO_2, we encounter the overlap of development and validation. If new decompression procedures are not firmly based on established experience then some laboratory trials or chamber dives are needed, and this should be called development rather than validation. Here judgement is needed to design a test plan appropriate to the degree of newness and uniqueness of the procedures.

For most *relatively established designs* I would accept a dozen or so clean chamber dives as adequate evidence that it is time to move to the stage of provisional use at sea.

If you are going to skip the "provisional" at-sea steps and want to proceed directly from the chamber to the stone tablets then hundreds of man-dives in the chamber may not be enough. By this I mean that it is unwise to present tables as "finished" based only on dry-chamber laboratory experience. When the laboratory has provisions for hard work in cold water using field equipment, the step to the sea is small.

But I am not advocating expensive "sea trials" for their own sake, unless the organization needs the exercise. A responsible diving outfit should have the capability to use provisional tables for an appropriate period *within the scope of normal operations*. The conditions for provisional use of new tables would vary considerably depending on the nature of the operation and the tables, but would involve a few principles. One, as we have noted, is to take small steps.

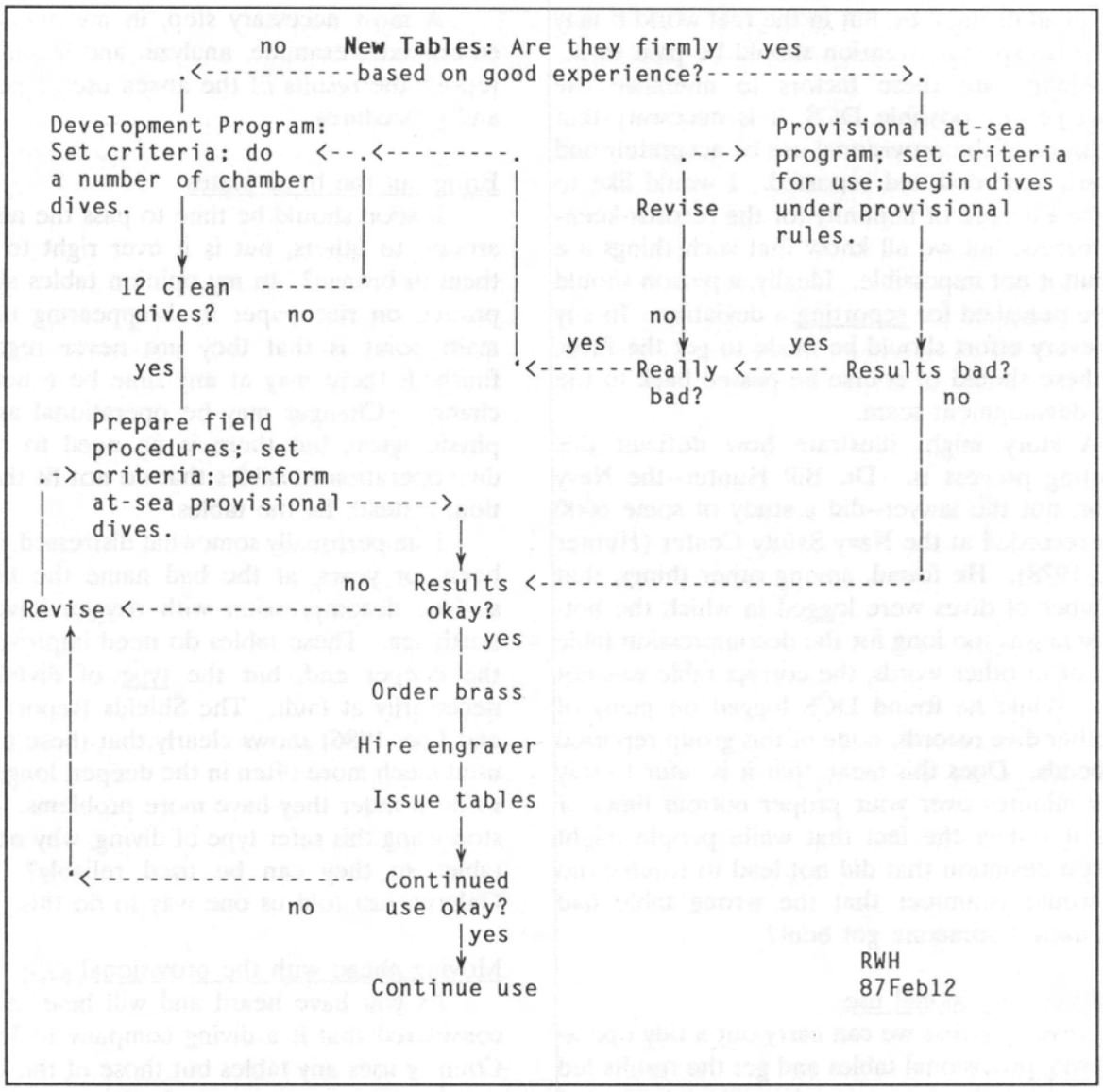

Figure 1. Steps in table validation.

Requirements for initial use of provisional tables

Provisional tables should be used at first by a competent crew, one that already knows the setting, the job, their equipment, the tables, and their operating procedures. The crew should know each other, and the supervisor should know his divers well. New tables should not be introduced for the first time under stressful conditions of weather, equipment, current, language, client pressure, and so on. Some have suggested that divers acknowledge with their "informed consent" that the tables are provisional; personally I believe this would be appropriate only in certain cases. Tables that represent sufficiently small steps away from procedures acknowledged to be reliable by all concerned--including the divers of course--should be useable at sea without informed consent.

As important as the crew and the chamber, it is critical that *management* be involved and aware of the situation. The requirements offered here are tough enough when everyone is cooperating, and do not need the additional stress of obstructive or non-participating management.

The person in charge should be trained and have some experience in dealing with decompression sickness, and should have all the equipment, gases, drugs, communications, and know-how to handle a DCS event. In truth, this should be the

case on all diving jobs, but in the real world it may not be, so special attention should be paid to it.

Along with these factors to minimize the impact of any possible DCS, it is necessary that the results of the provisional use be accurately and honestly recorded and reported. I would like to suggest a degree of impunity for the records-keeping process, but we all know that such things are difficult if not impossible. Ideally, a person should not be punished for reporting a deviation. In any case every effort should be made to get the facts, and these should of course be passed back to the table development team.

A story might illustrate how difficult this reporting process is. Dr. Bill Hunter--the Navy doctor, not the lawyer--did a study of some 6000 dives recorded at the Navy Safety Center (Hunter et al, 1978). He found, among other things, that a number of dives were logged in which the bottom time was too long for the decompression table used; or in other words, the correct table was not used. While he found DCS logged on many of the other dive records, none of this group reported any bends. Does this mean that it is safer to stay a few minutes over your proper bottom time, or could it reflect the fact that while people might report a deviation that did not lead to trouble, no one would volunteer that the wrong table had been used if someone got bent?

Results of provisional use

Presuming that we can carry out a tidy operation using provisional tables and get the results fed back to the table team, one other principle needed is that if things do not go well enough, additional changes or revisions will be made. Any DCS should be investigated, and necessary corrective action taken. Often procedural or operational changes will suffice at this stage, but the tables should be changed when that is needed.

Judgement enters again in determining when enough provisional experience has been accumulated. I would expect that after only a few or a few dozen successful dives the provisional rules could be relaxed, with tougher jobs undertaken and the tables used by less experienced crews. The treatment capability should be standard; this might be an excuse to bring that aspect of an operation up to speed. If everything else is done well it will not be needed very much anyway.

A most necessary step, in my opinion, is to consolidate, examine, analyze, and if appropriate, report, the results of the at-sea use of new tables and procedures.

Bring out the brass plates

It soon should be time to pass the new tables around to others, but is it ever right to engrave them in bronze? In my opinion tables should be printed on rice paper in disappearing ink. The main point is that they are never regarded as finished; there may at any time be a need for a change. Changes may be operational as well as physiological, but there is no need to restrict a dive operation to tables that do not fit the operation; instead, fix the tables.

I am personally somewhat distressed, and have been for years, at the bad name the tables for surface decompression with oxygen have in the north sea. These tables do need improvement in the deeper end, but the type of diving is not necessarily at fault. The Shields Report (Shields and Lee, 1986) shows clearly that these tables are used much more often in the deeper, longer range, so no wonder they have more problems. But why stop using this safer type of diving, why not fix the tables so they can be used reliably? (Andre Galerne just told us one way to do this.)

Moving ahead with the provisional step

As you have heard and will hear more, it is considered that if a diving company in Jones Act Country uses any tables but those of the US Navy then lawsuits are guaranteed. We cannot do much about the legal climate that leads to this, but there ought to be some way to improve decompression tables. In preparing for this workshop I asked a diving company executive how to get new tables into use and his answer was, "Do it outside the USA."

If this workshop does not accomplish anything more, I would like to get the concept of *provisional use* acknowledged, accepted, approved, agreed upon, or somehow made useable.

Therein lies a story. Several years ago my colleagues and I prepared some state-of-the-art deep bell/bounce tables for a diving company. We sent them out labelled "provisional," with the comment that they should be so regarded until their operational people had shaken them down

with regard to operational details. To prepare the tables we had conservatively recomputed and revised the format of an older and well established set of tables that had been in use for several years. For a variety of reasons both operational and physiological there was a tough case of DCS. The plaintiff's attorney zeroed in on the fact that the contractor was using "experimental" tables. He even asked me if they had been tested on animals! The case settled out of court so I did not really find out how serious this would have been in front of a jury.

We are not primarily concerned here about the bizarre legal problems of commercial diving in the US, but our client NOAA and others of you here need the ability to get new tables. Sometimes this is for improved reliability, but more often it is to be able to use some new equipment or do a task that just was not thought of when USN was doing its table development. These things have to go through a provisional stage one way or the other. Lets make it legal and proper to do it on the job in small steps. To do this we need agreement by various agencies and a consensus of the experts in the field that this is the appropriate way to proceed.

Summary

At some point, either after some developmental chamber dives or by conservative modification of established procedures, it is necessary to begin using new decompression tables in the water. This should be done by taking careful small steps, using new procedures at sea under somewhat controlled conditions, always with the capability to treat DCS, and with good supervision, documentation, and feedback. This provisional step needs to be acknowledged by all as not only beneficial but necessary.

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DISCUSSION AFTER DR. HAMILTON

DR. HAMILTON: I would like to end by asking a question of Jim? How do we go about doing this?

MR. SUTTERFIELD: Bill was talking about having an informed consent form signed. I think that an informed consent form is an excellent idea; however, make sure that you disclose everything. The thing that is much worse than having a form is having a form that is not complete, because if there are some risks that you do not disclose, you are automatically going to get nailed. So, just make sure that you do; there is nothing wrong with disclosing all the risks. If someone is serious about undertaking it and if it is the proper step where those tests should go forward, then I think you will get people to do that.

DR. ELLIOTT: It was good that you excluded conservative development of new tables from this discussion, the development of new tables. I think that is very important to distinguish.

We know very well from previous efforts that there are collaborative research projects where there was no single budget holder, neither the oil industry or the diving industry. Therefore, if the developed table is to be non-proprietary, who is going to pay for the development?

On your chart there was a sharp intake of breath when you said 12 dives and then you could do something. I think you will find that the discussion would focus on that. Please, could you answer the first question?

DR. HAMILTON: You mean who is going to pay for it? Jan Merta (Canadian Oil or Gas hands Administration) will pay for some of it. I really do not have the answer. Shell, maybe?

DR. ELLIOTT: No. There is no single budget holder in the oil industry.

DR. HAMILTON: That is right. And particularly now and in the next few years, we cannot expect to have a lot of money. Which is why I am asking for procedures that involve modest laboratory steps to eliminate the disasters, and then go carefully into the field. This is paid for by the client who needs the work. It costs a little more to do. The company has to absorb the records keeping task, the analysis, and a few other things. The only way that you are going to make sure that something that is new works is to go and use it.

As for issue of 12 clean dives, here is the step between a development program and a validation program. If you do a development program and have your criteria set up and everything and you can do a dozen dives that are good, then it is safe to use those provisional procedures in the field. But, the number 12 was put up there to spark the discussion.

DR. LAMBERTSEN: To keep a focus on what we are talking about, look at the word, "table." A table could better be called a "procedure." Then, it could be called a "set of procedures," because a table is one episode for one kind of dive and then that dive is over. That is a table for that dive. A set of tables is many of these.

When one talks about how much investigation--not numbers, we are saying how much investigation--is required to evaluate a diving procedure, one philosophy goes with one kind of diving as opposed to the many other kinds of diving. You may be dealing with many hundreds of diving tables for a given procedure. You must evaluate the whole procedure or you will not know whether or not that table fits inside of that whole procedure. Let us not start worrying about how many numbers one needs for something without seeing what it is we are talking about evaluating.

That includes the short and the long, the deep and the shallow, in terms of evaluation, because unless it all fits together, then it is not a rational set of procedures.

CAPT THALMANN: Two things. One, it appears Bill has drawn a safe flow chart that we use to develop tables already. So, what is new?

Being coldly objective, so this should not be taken personally, I mainly see the individual--from your standpoint--is spreading out the liability.

Let me give you an example. When you start out with a novel table like the Constant Partial Pressure Table, where there is no data base to start with, you need a large dive series to find out where you are before you can go out in the field. In another case, the U.S. Navy was faced with a unique diving operation that required long, shallow multilevel dives, for which the Diving Manual was absolutely unsuited. A procedure was put together, approved and put out into the Fleet without one man dive ever being done. Even though it was an absolutely unique procedure, it was totally based on accumulated experience. So, even within the confines of the U.S. Navy, some procedures are put forward without any testing, as long as the individuals agree that it is well within the realm of experience. You can make a judgment to decide whether or not that experience is valid. But the Navy is also willing to accept the liability for that decision. In other words, if things go wrong, they assume responsibility and have the mechanism for following up on it.

I think what your procedure is trying to do is maybe to take a smaller organization that may have a very large exposure and somehow get out a procedure which will spread the liability, because the logic to your procedure is very well founded. That is how it is done, except in the Navy, which has the ability to accept its own liability. A small diving company may not be able, in and of itself, to assume all of the liability, so then you hope that a consensus of experts will somehow absolve you of that. I wonder if our lawyer could say if that is really of any help?

Does the fact that a bunch of experts agree that it is a reasonable procedure in any way change the liability?

MR. SUTTERFIELD: Well, it certainly would knock out a claim for punitive damages, I would think, and I think it would mitigate the damages you have because you are acting totally responsibly and you have leaned on the best minds possible that you could find to do the right thing. It may very well walk you out of the courtroom free and clear.

As for risk, generally that is what the insurance industry does, it spreads the risk. So, in effect, they are spreading the risk; however, it is not spread as thin as it perhaps could be.

CHAIRMAN SCHREINER: At this point, I would like to make a belated introduction to you of the gentleman to whom this organization, this group around the table, owes its existence, having been convened in this manner. This is Mr. Elliott Finkle, who is the Director of the Undersea Research Program of the National Oceanic and Atmospheric Agency, NOAA.

MINI-PRESENTATION: THE SPONSOR'S PERSPECTIVE

Elliott A. Finkle
Director, Office of Undersea Research
National Oceanic and Atmospheric Administration

MR. FINKLE: Thank you. I am really impressed with the group we have here today.

Let me give you an example of why I wanted to sponsor a workshop of this nature. Something happened a couple of years ago. A Federal agency gave a grant to a university that computed a set of tables for exiting from an emergency recompression schedule.

I happened to be on the board of that program and when I saw that these schedules were being printed and distributed, I asked them how they could do that. I said, "Well, who validated them? Who said you could send those out? You just cannot do that."

Anyhow, to make a long story short, one of the people who got those schedules used one of them. I had asked him not to use it, but he did. The nurse who was in there performing a 6A or whatever exited under those tables and got bent.

So, I said to myself, "There has to be a way where we can validate tables before anybody can just put them out in the community." We need something that, for a new table, says somewhere that experts have said, "That's a good table. Let's use it."

The other reason is, of course, that NOAA publishes tables in its NOAA Diving Manual. We have just developed a new set of tables that Bill Hamilton developed for us, and we are going to publish them. Even though they are developed, the tests done and they seem reliable, there still has to be a way of validating, of saying, "Hey, let's use those tables." That is the reason for the meeting today. I appreciate you all coming to it.

CHAIRMAN SCHREINER: Thank you for your comments. Maybe CDR Hobson would comment on the point that was just raised.

CDR HOBSON: What Bill Hamilton is proposing is in some way being done by the commercial companies. It is also the approach that has been taken by the Navy. It is an attempt to coordinate it at perhaps a somewhat higher level.

I also heard the sharp intake of breath on the 12 dives, but I failed to realize the development program. You really did not say what your development program is. If you do 20,000 dives in your development program, after 12 dives you can say, "Go for it."

Anyway, if you shift and get these new tables for commercial purposes out to the field in a big hurry, then that is going to put a larger onus on the commercial operators. Now, instead of going out with a set of tables that they feel fairly well confident with because somebody has done some work on them, they are just introducing them and checking on the introduction. Now they are doing the validation. That is a whole different process, because you have to control a lot more of the factors to do a proper validation of these tables. You have to virtually build a team and set up a program to look after this specifically, if you are going to do it correctly.

If you are going to take the onus away from the people who developed the tables and put it onto the contractors with the hope of getting them out there faster, especially on a new development, that is all very well and good. But I do not think the commercial people are keen on setting up a validation team that is going to go from platform to platform to station to make sure that these things are introduced correctly and that the validation procedures and the reporting and the data recording are done to a standard that somebody can accept, especially--if as we have already heard--they are skeptical of how the militaries and research institutes do it.

MINI-PRESENTATION: U.S. NAVY DIVING PRACTICE

CAPT Dick Garrahan, USN
Naval Sea Systems Command

CAPT GARRAHAN: Yes, like LCDR Hobson I am not a doctor, and like Dutchy I am an operator. I came in the Navy in 1956, went through dive school in '59, and have been in an active diving billet ever since. In regard to the U.S. Navy Decompression Tables and their validation, I think Dr. Harvey and Dr. Thalmann have pretty much covered that area. We do maintain a requirement to have our people dive in accordance with Navy-approved diving tables. That is because we have a number of different types of divers out there, from scuba to saturation to the rescue/salvage dives, etc. Each mission has a particular scenario, and therefore decompression tables are tailored to the decompression needs of each community.

You know, we realize that not all of the tables are perhaps as reliable as we would like them to be, but they are very good sets of tables, we feel. We do not authorize nor do we accept any tables that have not been validated. As a very quick example, we had a young lieutenant recently who felt that the residual nitrogen timetable in the Diving Manual was not adequate for his particular command. He developed his own and signed his name to it and promulgated it to his underwater construction team unit, all without his CO's knowledge. Needless to say, that was a very embarrassing lesson for that young lad.

As another example, I just received this week a set of tables from some civilian, who I believe had pretty much extracted them from the Navy Tables, plasticized them, patented them and is selling them in the scuba shops. He sent them to the Navy asking if we were interested in buying them. I looked at them. His range of operation was 40 feet for 200 minutes to 140 feet for 20 minutes. These were repetitive dive tables, by the way. We know the Navy operates at 40 feet for 300 minutes, 190 feet for 40 minutes, repet tables. So, we said, "No, thanks."

Four quick comments in regard to what we have been discussing today. We started the presentation this morning by indicating that we, the diving world, if you will, pretty much are using the U.S. Navy Decompression Tables. The very first question that came out was: Why are we not testing decompression tables properly? Is it money or is it inexperience?

On behalf of the Navy, I feel that we, the Navy, are properly testing and validating our decompression tables.

In response to the statement that Navy decompression tables for shallow dives are inadequate, i.e., 4 to 6 hour dives each day, dive on the weekend and get bent on Tuesday. We, the Navy, routinely dive shallow dives 4 to 5 hours daily with both our underwater construction teams and Special Warfare units and find our tables to be quite adequate.

In response to the comment that the Navy does not decompress in accordance with its own tables, because the master diver states he has never dived to the exact depth and exact time on the decompression table, I say, please do not take his word as gospel. I believe the majority of Navy diving commands are diving in accordance with the dive tables as they are written.

Regarding technology exchange, everything that the Navy has in the Diving Manual is free. It is available to anybody that wants to procure the Diving Manual.

Unlike the Navy, where we have a central agency or organization that is accountable and responsible for maintaining and updating decompression tables, it appears that the civilian community does not have that organization. I am glad to hear the question brought up of who would do it? It appears to me that the civilian community does need to look into that.

We are encouraged by this meeting. We are anxious to have the civilian community put as much time and money into validation of their decompression tables as the Navy has put into theirs. One sad fact of life: We have found out very recently that there is no Santa Claus, and so we have taken on programs--joint programs-- with the Canadians and the UK in an effort to join our

assets and our funding. It appears that the recommendation is that you folks need to develop a similar type of program.

DISCUSSION AFTER CAPT GARRAHAN

DR. BENNETT: Yes. I thought the plan for validation really was very similar to the sort of thing we have done at Duke in table testing, as Bill Hamilton knows, although we certainly changed from the 12 and went back to 30 in terms of number of test subjects.

I became concerned as I heard the question as to why should a commercial company, for example, change what it is doing now? It is quite happy with what it is doing. It is getting down to whatever, 0.3-0.4%. Why should anybody want to use this, other than perhaps the government?

Now, if Elliott Finkle (NOAA) wants to produce tables, is it not possible, then, for him just to say, "This is going to be a validation method. We are going to come forward with a list of things to be done and if anybody puts tables through for testing, this is how it will be done."

Then you come to, "Who is going to pay for it?" We have been hearing again and again that there is no money.

So, I keep coming around in a circle with this, again and again, as to where we are really going. We can come up with a plan for validation. We can say we are going to do all of this, but unless some funds are there, we are going to have trouble doing it. Even if we do do it, we are still going to be faced with the legal issue. I have great faith in the consensus around the table, but I have no faith at all that it would stop somebody from jumping in and suing you as soon as they thought they had a case.

The whole problem of validation of decompression tables is a very, very difficult one in the United States today. We have to think very seriously about how we can attack those two particular areas: the financing is one, and the legal issue is another. If we do not do those, we can write anything we want in gold plate, but in my view it will not in fact solve the problem.

CAPT HARVEY: I wish I could argue with you, but I know you are right Peter.

What Bill Hamilton proposed when I worked with Dr. Lambertsen he allowed me the privilege of going out to sea to work with neon diving tables developed by Dr. Hamilton's lab at Ocean Systems. We first checked out some neon dives in the lab. But then Ocean Systems did something that really, I think, sort of protected them at that point in time.

Number one, they trained the diving team that was going to try the thing out, very carefully. The supervisors were carefully briefed; the team was carefully chosen. They provided a doctor, in this case myself, that was thoroughly briefed on what we were going to get into out there, and we had contingency plans well in mind. They set up good radio links, good chambers, dove in a good situation aboard a ship with adequate treatment facilities. What I am saying is, they did their homework so that when they went into the sea they were ready. We did have some decompression sickness and we found some limits in the operational situation that were worse than I, at least, had anticipated.

They did their homework. They set the thing up, put it out to sea and tested it. In spite of the decompression sickness, we came out of it okay. There were no lawsuits. Homework and careful preparation for the at-sea trials is a part of your key. You can not just trust diving teams because they are trained in diving to be adequately prepared for the sea trials.

DR. YOUNGBLOOD: Well, there was one more audible gasp that went out, I think that Dr. Hamilton has either been extremely fortunate or has not observed some other people's problems, because while it is very rare, I disagree, regretfully, with his statement that catastrophes do not happen. He did not actually say that. In experimental development of decompression profiles, decompression sickness sometimes occurs that does not respond even to the most immediate treatment, and it can leave lasting ill effects. I think several of us have seen that.

LCDR HOBSON: I would just like to throw this out just for consideration. Sitting on the fence here, sort of a neutral between the U.S. Navy and the commercial interests, I find it very interesting to find on one side the commercial interest, saying,

"We have great problems with the USN Tables." The scientific people saying, "We have great problems with the USN Tables," and the USN standing up and saying, "You're nuts. We have no problems with these tables."

I go back to Dr. Thalmann's question: What is the difference with the USN divers, then, because our basic research that led into the DCIEM '83 models said, "There are problems with the USN Tables."

The other thing that was brought up that I think is very important is that the USN, CAPT Thalmann, complained about not getting any feedback from the commercial side and from the other university research sides. I think that is a very valid point. The last research done was perhaps in 1940, or whenever these tables were finally finished. There had not been any follow-on since then, but there have been a lot of new techniques developed, people are looking a lot closer.

One of my best analogies when I give my standard dog and pony show, is the 11th Commandment, written on stone. "Thou shalt not defile the USN Tables." Because people have assumed they were created in perfection, they were done perfectly. That is not the truth. But what should be happening is, the navies have the research facilities, they have the capabilities, they have the proven procedures, they have the will, but they evidently do not have the mission. I mean, the surveys show all the diving is done shallow. They have these deep procedures but they do not use them. People who were using the deep procedures are complaining about them, and that link is being missed. If anything can come out of this, some way has to be made for the navies that have the procedures, report writing capabilities, data collection and all the good stuff to take on the cases and get the data back. There is not anybody from the Navy or from commercial or otherwise who at the end of the day is not intent on making the thing better for the man going in the water.

CAPT THALMANN: Everybody involved in developing tables was very honest about the problems with the tables. The EDU reports do not say you are safe per se. Van der Aue said there was a 24% incidence of bends in the Navy tables.

LCDR HOBSON: Yes, but you jumped all over Dutchy Holland when he suggested that there were problems with the USN Tables.

CAPT THALMANN: No, I did not. I said, "What's different about Navy divers, because if there are problems with the USN Tables, the Navy is going to have them as well?"

LCDR HOBSON: They do not dive them.

CAPT THALMANN: They do dive them. It is not true that they do not. The USN, I think, is its own worst critic, because they have spent a lot of time and effort going back and relooking at their own tables, within their capacity.

Now, when we say that the Navy is not having problems, it is because for the dives they are doing, they are not having problems. If all of a sudden the Navy was having to dive to 350 feet on helium and do it regularly on a mission, they then would have the mission to look at those tables. The U.S. Navy has a mission to look at long shallow multi-level dive tables right now.

LCDR HOBSON: What I would suggest is that the indication of problems is here. When do you want to find out that you have problems? When you have to go out and do the mission? That is not the time. If there are indications out here that there are problems in those areas, then perhaps you should be looking at those, because when push comes to shove, and all of a sudden you have to go out there and do it, that is not the time to find out you have got problems?

CAPT THALMANN: Okay. Let me just close with a story. There has been a lot of talk, for instance, about special tables for sport divers. The most besieged part of the Navy tables in that regard has been the no-decompression ones. I have heard individuals get up and say that these no-decompression ones do not apply to sport divers because U.S. Navy divers are somehow different and they were tested differently and whatever.

Okay. We have, within the last 12 months, gone back and done another 200 dives on the No-D tables and once again they have come up absolutely clean.

So the people doing the dives do go to the leaders and they do listen to what people say, but when the Navy says they are not having problems with the tables, it means their experience with their procedures satisfies their particular need.

Now, Tom Berghage's analysis says that there is a 1.5% incidence of bends when using the Navy tables. Now, Dutchy Holland says that is inadequate (too high). So, he has problems; the Navy does not. The Navy is willing to say that a 1.5% incidence of bends is within their mission. I am not going to say it is not a problem, because you have to look at what kind of bends they are. But when a commercial company says, "No, no. We can not have 1 bend in 10,000 man dives. It's too much." Then I would say that it is probably not from a physiological standpoint, it may be from a monetary standpoint.

LCDR HOBSON: But you have admitted that the only reason that it is 1% is because of the large bulk of short shallow dives that draw that down. When you went into the critical areas, those three or four rough profiles, you were running at 3 to 4%. That is in the Fleet where they could be as much as 10 minutes out and 10 feet off.

CAPT THALMANN: I think that if anybody thinks that the U.S. Navy thinks its own tables are sacrosanct he should read the EDU report that came out in August [that takes] another look at the air tables and read it very carefully. Look at the tables that were the result of that study, which are longer than the DCIEM tables (Ref. 36 in CAPT Thalmann's paper).

The Navy is constantly evaluating itself and does not think that their procedures are perfect; maybe other people do. But I do not think they do and I think they are very open with themselves about it. If we go to a meeting and hear that someone is having problems in certain areas, we take that to heart and go back and look at it. We do not live in any kind of a shell. The example I stated; We went back and spent a lot of time and money looking at the No-D limits because we heard all this stuff about how awful they are. We cannot see a problem, because every time we test the bloody things they work.

MINI-PRESENTATION: VALIDATION IN THE COMMERCIAL WORLD

Michael L. Gernhardt
Ocean Systems Engineering, Inc.

MR. GERNHARDT: All the points that I was going to make have already been made, but I think in light of this recent discussion here, I will just pick up a specific example of commercial decompression development that I think will focus some of the issues that have been raised today, especially just recently.

First of all, this program has been ongoing, but has been stopped for two interrelated reasons, the lack of clear validation criteria, and cost.

The program involved developing decompression procedures for working at multiple depths on platforms. The Navy procedures for this were unacceptable to us for a number of reasons. Firstly, there would be a requirement to do sur-d/-O_2 at 70 feet, and the big gain for us is to get shallow on the way. We are actually off-gassing, and continuing to do useful work.

Secondly, the bottom times imposed by the repetitive group letters are restrictive and only applicable for inspection work, as opposed to construction or maintenance work. And thirdly, the procedures themselves are too complicated for the average diver.

So for this reason we tried to redefine a whole new matrix of time/depth profiles, and we undertook a development process. I will kind of step through what we had in mind, just as a sounding board.

Basically, the process involved a comparison of the procedures that we desired against the classical Haldanian models, although we felt these would probably be unacceptable for those time and depth limitations. Nevertheless, they provide data points that we knew we had to be more conservative than. It also involved a comparison to a number of decompression tables with proven field results for which we had specific records. This was all done in conjunction with the University of Pennsylvania where we had access to very well kept records and specific incidences of bends. Finally, we cross-referenced a newer model of gas bubble dynamics. We analyzed the things at different points in the profile and always selected the most conservative criteria when there were options.

The second phase of validation is that we tried to review the procedures and eliminate potential for abuse. We find that in the Navy tables this can happen a lot with such things as a smooth transition from normal exposures into the extreme exposures. I know of many cases of bends that have resulted from the supervisor having extreme exposure options easily available to him in 10-minute increments, so that there was a propensity--a possibility--to run over on bottom times and maybe to try to compensate with some ad hoc procedure that was not sufficient. Just simplifying the instructions and the operational complexity of the procedures reduces the potential for abuse.

The third phase that we had planned to do parallels what Bill said: Go into a laboratory testing phase where we would do enough tests to ensure that we would not have a catastrophe, the idea being to get out into the field as soon as possible with the same controls he mentioned--making accurate time/depth records, using the doppler, and so forth. I think this process, if we can get through that laboratory phase with minimal testing, reduces the cost enough to allow us to get out into the field and get cost effective trials done under truly realistic operational conditions at really no great cost to anybody. Then the final phase is the accurate data base to follow up on.

DISCUSSION AFTER MR. GERNHARDT

CAPT GARRAHAN: Two things. Once again, let me say we realize our tables are not as accurate as we would like them to be. However, they are tailored to the needs of the military.

MR. GERNHARDT: Yes, absolutely. That was my point.

CAPT GARRAHAN: When you indicate that they are unacceptable to you folks because of your sur-d requirements or to get the guy on deck so you can move the barge, et cetera, et cetera, that is your problem.

MR. GERNHARDT: That is exactly what I am saying.

CAPT GARRAHAN: When you say there is an option to slide, if you will, into extreme exposure tables because they are there, again, that is your problem because in the Navy extreme exposure tables require specific authority from the commanding officer or higher. So, you know, you are talking apples and oranges.

We, the Navy, the EDU, does not get money from the commercial industry to develop and validate tables.

MR. GERNHARDT: I think my point was not so much that the Navy tables are bad. I think it just reiterates what you said. The specific operational requirements and abuses that occur in the commercial diving industry are different from the Navy.

CAPT GARRAHAN: But they are a result of your operational requirements, and not the tables that the Navy has developed.

MR. GERNHARDT: I think that is safe to say.

CHAIRMAN SCHREINER: I think Mr. Gernhardt has appreciated that, really. It was unfortunate that it was perceived as criticism. It was really not. I think the semantics of it should have run that the tables that the Navy provides are not appropriate for his mission.

MR. IMBERT: I would like to defend the U.S. Navy tables. As you know, at the commercial work site they may dive the exceptional exposures as a routine procedure every day for 45 days. They do repetitive diving using surface decompression. So, no wonder that they achieve bad results. We should be more specific in saying that the U.S. Navy tables are bad or good. In fact, they are very much like what the computer does, the same time or the same people with the same knowledge and tables here. If you take the U.S. Navy inwater decompression tables, they have exactly the same results as French tables--pretty good when they are shallow and not too long. But in the deep and long range they have 1% or 2% DCS, which is equivalent to any of the other tables presently available.

What is difficult nowadays is to achieve safe surface decompression for long and deep dives. That is where a lot of the trouble is coming from. That is where the bad reputation is. Believe me, there is no easy solution to that. I do not know any tables that can achieve reliable and safe results for that situation.

Now, as to what should be acceptable or not acceptable, I think that one should be very cautious in examining the data for use by the different data banks. It is extremely difficult to get the information from the work site. It is no wonder that in the laboratory you get better accuracy and a higher incidence rate. From offshore, we only get reports. We may have rumors, commands, Telexes, investigations, etc., but we are far behind the actual way the decompression was done. We are optimistic, we recognize it. There is a lot of difference between the data that has been presented in Tom Shields' report and the data that you present today and the ones we get. We have the range from 0.5% to 2% to 5%. So, we should be more cautious about the protection of data. Also, we should be more specific when condemning the U.S. Navy tables.

CHAIRMAN SCHREINER: Thank you.

MINI-PRESENTATION: DECOMPRESSION IN TUNNEL AND CAISSON WORK

Eric P. Kindwall, M.D.
Director of Hyperbaric Medicine
St. Lukes Hospital, Milwaukee, WI

DR. KINDWALL: I would like just to make a few points to try to keep us focused. On the validation of tables, our laboratory was faced about two years ago with developing a set of new decompression tables for compressed air tunnel workers. Not having the ability to use a "validated model," we had to validate it in another way. It was handy that we have computers, because using Peter Edel's computer in New Orleans with a memory of 15 years of successful and unsuccessful dives, we kind of asked the computer to paint a curve that was representative, more or less of successful, or what we would predict to be successful, dives. This was based on previous dives, successful dives, not necessarily a model; but a "16-tissue" model was then used to flesh out the points in between the data.

This is one way to get validation before you risk getting sued later on. Now, following this empirical approach, I would like to just put in a point about the use of tunnel schedules as a tool for all of us. I think their use may not have occurred to some in terms of data gathering. All of us, diving and tunnelling, are concerned with gas movement in and out of the body. It is all the same thing, really. And, divers often decompress in air or in gas, not always in the water, just as tunnel workers do.

Additionally, air is poorly understood because we are still playing with air tables. The main problem with all of these is the long deep tables. Everyone says, "Well, that's where you always have the problems. The short shallow table is no problem."

That indicates that the model is still imprecise. We get along fine, until we go deep and long, then we have a problem. We have a perfect opportunity with decompression tables of tunnel workers to study the longest possible times: Seven hours exposure per day at 30 feet. That is done every day of the week. You have a beautiful opportunity for very long exposures, to find out what is really going on in the body.

All of the tunnel tables fill the envelope completely. Navy dives are often bounce dives or spot dives. They do not necessarily fill the table time. "Well, I got away with a 100 foot for 40 minute dive. No problem." Except that it was to not quite 100 feet for not the full length of the table dive and so forth. It is always true. Every day. The tunnel/caisson records are superb because they are scribed on a little revolving recorder by law in every state, so you have a beautiful solid example.

The tunnel exposures are also never greater than four-foot increments. There is a brand new schedule for every two pounds (psi). So, it is not the case of only a tenth of the dives being valid. You are pushing it right up to the pound, every single day. You can bet that the company is going to hold down to the minimum--if you need 14 pounds, they will not do 14.5. They will hold 14 and take the water if they have to. So, they push every table every day.

And vast numbers can be accumulated. For dives we are always talking about, "Well, we got 12 successful dives here. Maybe that's okay." How would you like 3,700 man decompressions from just 22 pounds? We have got that data.

Conditions are identical for every pressurization. Divers work in the water. One guy fights the current and the other guy does not. Tunnel workers all do about the same kind of work. This is superb data in that sense. And the temperature is a constant 54 degrees year round, unless you are concreting and then it gets a little warmer.

There is one disadvantage in that, unfortunately, all the data from these tunnels are for habituated "divers." These people are totally habituated (i.e., "worked up") and you are not going to see the virgin diver, it is an impossibility.

Finally, another disadvantage with them, tunnel workers historically have been very stoic. The only way to get a true bends incidence out of them is to ask them to report anonymously, because if they report bends, they know they will be

recompressed too much and tossed off the job. But you can by anonymous reporting get a very good idea of bends incidence.

One final point. I have tested tables the old fashioned way, bending people, bending myself. The problem now is formidable because of an Australian paper presented at Kobe in September.* There was a prospective study; 30 divers were looked at, all came in to be treated for bends. Twenty of them were neurologic hits; these were tossed out, and we looked at the 10 people who had pain-only hits. These were neurologically negative. They were treated adequately (the Australians do a good job with that sort of thing). Then they were followed up a week later and a month later, using psychometric testing, cortical evoked potentials, EEG's, CT scans and repeat neurologic exams.

At one week--pain-only bends--60% had aberrant psychometric testing, dropping to zero at one month. Forty percent had abnormal EEG's at one week, dropping to 20% at one month. Cortical evoked potentials were unchanged; there were no disturbances. One of the ten had an abnormal CT scan at one week. Two had abnormal CT scans at one month, showing brain atrophy.

At this point, we can not distinguish between Type 1 and Type 2 bends. I think that table testing the old way of looking for bends should cause us to be very careful about doing this to subjects. I hope Dr. Weathersby is going to help us out here so we do not have to do it the old way any more.

*EDITOR'S NOTE: The reference by Dr. Kindwall is given below. The published paper includes more and slightly different data from that quoted, but the conclusions are intact.

Gorman DF, Edmonds CW, Parsons DW, Beran RG, Anderson TA, Green RD, Loxton MJ, Dillon TA. 1987. Neurologic sequelae of decompression sickness: A clinical report. In: Bove AA, Bachrach AJ, Greenbaum LJ Jr., eds. Underwater and hyperbaric physiology IX. Bethesda, MD: Undersea and Hyperbaric Medical Society.

A TENTATIVE ASSESSMENT OF THE FIRST DAY'S FINDINGS

H. R. Schreiner, Chairman

CHAIRMAN SCHREINER: At this point, it is my assigned task tentatively to assess what has transpired today. I would like to modify this task a little and tell you what I think I heard. Since there is not complete agreement on everything that was said, it is entirely likely that these remarks may cause somebody to feel I did not reflect his views. Please bear with me.

I think we clearly showed, unfolded for all to see, the complexity of what I call the dive envelope. The dive envelope goes beyond depth, time, gas or gases. It involves the operational, the environmental situation. For example, the situation ensuing with diver heating versus no diver heating or the habituated versus the non-habituated individual. It is subject related. The dive envelope reflects a very large number of variables.

In addition to that, there are exceptional exposures that require emergency responses or emergency procedures. We have heard about high stress diving which may call for extraordinary decompression procedures.

Basically, though, the state of the art, as it unfolded today, is based on a fairly massive body of experience, going back--if you take tunnel "diving"--about 150 years, not all of it recorded of course. And this experience, the reporting, recording, and analysis of this experience is in an imperfect state. Imperfect because of what we heard going on in the field. Imperfect because of proprietary consideration in the commercial world. Imperfect, also, because we really have no sharp end-points. We talk about DCS and we hear it characterized as antiquated as an end point. Maybe it is. And so then, when we record this experience, this data base, we have to ask ourselves: What are we recording?

As we heard, we have to be prepared to accept that the acute manifestations, subjective or objective, may not be the appropriate end-point for recording a "clean" dive.

So that leaves one with the overwhelming feeling that no matter what we do, there is an inherent risk in diving. I think no one in this room will deny that. It becomes just a matter, then, of minimizing this risk.

We minimize this risk, I believe, from what we were told by taking the data base and incrementing it systematically, incrementing it by proposing and testing concepts with the proviso that there is a clear scientific audit trail to the data base, that you know exactly how and why you are taking that new step. You take this new step, primarily because you wish to improve the safety of, or you wish to create new capabilities for the diver.

In any event, it would seem, from what we have heard, that the laboratory, the chamber, the wet pot, should serve as the place where this incrementally added concept is *tested*. It is not validated. It is tested. It is tested in a way that involves a full disclosure to the participating subject and informed consent. It imposes on the developer, on the person who increments our data base, an obligation to be knowledgeable, an obligation to use good judgment, and most of all--self-evident as it is, it needs to be said--to act responsibly. I think under these conditions one can expect such a laboratory tested incremental procedure to be declared by "standards," which need to be defined, to be available for operational testing on a provisional restricted basis, somehow marked as, "this has only been dealt with in the laboratory situation," no matter how realistically the laboratory tried to duplicate operational conditions.

From then on, if these tables were to go to operations, the *validation* of the decompression procedure would occur operationally at sea. That imposes an obligation to follow this experience, to record it appropriately, to share the experience to the extent that it is possible, so that a feedback loop occurs back to the laboratory to further increment the data base.

When we talk about validation, it was said that there is no definition of this term. So, I would like to propose one. I like to think that validation is nothing but establishing to the satisfaction of knowledgeable individuals the operational safety, effectiveness, and reliability of a particular procedure. This should be done accord-

ing to standards that have been argued about today, and cannot be resolved today, because we cannot even find complete agreement on what the end-point of a safe decompression procedure is.

So, I think that what we heard today represents to me a consensus of how we should move forward, how we should link the laboratory to operations, how we should create feedback from operations for physiological or operational reasons, back to the laboratory. That in itself cannot be proposed as a format of how we validate tables, but it describes a process that I believe most people, all people in this room, can agree to. That is my tentative assessment for the day.

DR. LAMBERTSEN: Please let me as honorary co-chairman, compliment you on the good sense of that phase of the task. I would like to add one further thought, that it is the *quality* of that whole effort that really counts. The quality of the process you described depends on the quality of the people who carry it out, the quality of thought and judgment of the people who carry it out. I believe that that is going to be one of the followons to the kind of thought process that you generated. How does one pull together numbers of people who are (such as in this room) able to think on these things, and put them to work at it?

CAPT HARVEY: The fact that feedback has been arranged and occurs does not mean you have solved your problem. It means you have identified and possibly quantitated the problem. The next step, then, is putting a priority on when and whether you are going to correct the problem. That comes down, again, to the basic question you started out with: Resources, need, and time frames in which to do it. The Navy knows we have some things we would like to improve in our deeper helium tables. We will get to it; but, right now, we are not using those tables enough to use what resources, time, and capabilities we have to solve that problem right at this moment. That does not mean we are going to neglect it. It means we are going to put it off temporarily while we do more important things. That must be kept in mind in all of these loops.

DR. PETERSON: Heinz, I very much like your definition of validation and I would like to get a clarification on one point. When you say this, "established to the satisfaction of the knowledgeable individual," does this cover not only establishing with actual dives with the procedure, but can it also include the basis of the relationship of a procedure to the experience available? In other words, being able to document to the satisfaction of a knowledgeable individual that a procedure has been so derived from the experience base that there is no question as to its efficacy.

CHAIRMAN SCHREINER: I think I used the term, "a clear scientific audit trail." That is precisely what you are talking about. That must be present, otherwise, you are not linking to experience. You cannot justify the next step, in my opinion.

DR. PETERSON: Right. So, we can validate a procedure with trials or with a demonstration on paper related to past experience. As an example, let us say that a saturation decompression procedure with a linear ascent rate of a certain value with a certain PO_2 has been used in operational dives and has produced a reasonable but not perfect results. Would anyone argue with the fact that a slower linear ascent rate with the same PO_2 should be considered anything other than operationally valid, as long as the faster rate was operationally valid?

CHAIRMAN SCHREINER: Well, you know, I cannot really take a partisan view of this because I would not be an effective Chairman, but I would leave this to the group. If I were temporarily to relinquished the Chair and speak for myself, I would say that I would like to see everything tested, even the safest assumption, because I am a believer in Murphy's Law. That is a personal comment.

DR. PETERSON: Murphy's Law has not been repealed.

CHAIRMAN SCHREINER: But it would not require, Russ, the extensive testing other steps might require because it is certainly a conservative step. But I leave it to the group to discuss wheth-

er it should be tested at all. I have given you my personal view, but that is only one out of many and certainly not a valid one at the moment, because I am, as you know, in "retirement" and do not have to live with the consequences of my comments.

CAPT THALMANN: I think the best tool is just do repeated pressure studies with the retrospectoscope. Of course, what Russ says is, given a set of reasonable assumptions, would everybody agree that they would work. Yes, if they work.

What I am saying is, no matter what procedure you try, if it is very different you are obligated then to follow it up and prove that it works, even though it has every indication that it will be all right. You can go through some very funny animal studies which show the things that were done, which everybody would have sworn up and down was better, and then increase the incidence of bends. So, no matter what increment you have or no matter whether you think you are making things safer or what, you are always obligated to do the record keeping later on to establish that what you did in fact is safer, even though everybody agrees, "Yes, it's got to be safer." You are still obligated to follow it up and prove that it is safer.

DR. LAMBERTSEN: May I emphasize, again, the word, "test." Make sure that it is included in a response to the problem Russ put on the table, which sounded perfectly sensible. The word "test" means whatever that responsible or informed group would consider appropriate for that particular circumstance. That encompasses the way to handle this. You are not going to have a mechanical process of equivalent testing for all kinds of circumstances. The word "test" has to be judged as well in terms of what it relates to.

A METHOD FOR INTRODUCING NEW DECOMPRESSION PROCEDURES

Jean-Pierre Imbert and Michal Bontoux

In France, in 1984, Comex was awarded a 3 year contract from the F.S.H. (Fonds de Soutien aux Hydrocarbures) to improve the safety performances of the French 1974 official air decompression tables.

Because a large number of parameters are involved in the safety performances of decompression tables, it was clear from the beginning that no:
- mathematical model,
- animal model,
- onshore laboratory manned study,

could be used to test the procedures and that the only way to validate the new tables was to dive them in actual worksite conditions.

It was also apparent that decompression sickness (DCS) incidence of the air tables presently available for commercial diving are still relatively low (around 1%-2% overall DCS incidence) and that a large number of man exposures would be required to statistically document any improvement of the new tables over the old ones.

The Comex programme was thus organized into 5 steps (Figurel no 1):
- evaluation of the existing tables,
- calculation of new tables,
- test of the new tables on selected worksites,
- modifications if required,
- presentation of the proposed procedures to French authorities for integration into the new diving regulations.

This paper presents this original method used to introduce the decompression procedures.

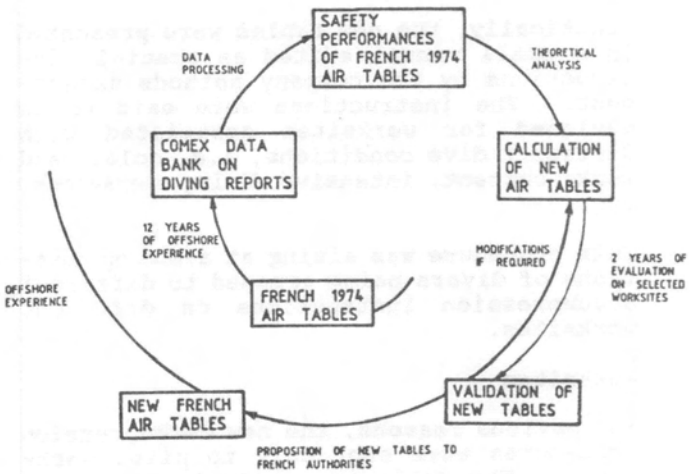
METHOD

Decompression tables

The starting point of the development of the new tables was a study carried out on the safety performances of the French 1974 decompression tables based on a computer processing of worksites dive reports(2). As a complement, Doppler bubble detections were also carried out onshore on a set of selected tables (11, 12).

The conclusions, which apply to the in-water decompression technique only, were that:
- dives of moderate hyperbaric exposure, corresponding approximately to the permitted bottom times of DOE memo no 7/86, were associated to very safe decompressions (0.1 % DCS incidence).
- deep and/or long dive exposures, corresponding to dives beyond the DOEn border line, were associated to a higher rate of DCS incidence (1 to 2% DCS incidence).
- divers using a safety margin in the selection of the table time had performed significant safer decompression when diving in the critical depth and time range.

FIGURE 1



METHOD USED TO DEVELOP AND VALIDATE NEW AIR DECOMPRESSION PROCEDURES FOR THE FRENCH DIVING LEGISLATIONS.

These findings were the basis of the calculation of the new tables which were designed to:
- remain identical to the original French 1974 tables in the range where safe results have been demonstrated,
- become equivalent to longer bottom times of the French 1974 tables elsewhere.

Effectively, the tables displayed deeper and/or longer decompression stops in the critical range. It was therefore possible to claim that the new tables were at any moment more conservative than the former ones, because:
- most decompression theories and models consider that deeper and longer decompression stops yield safer decompression,
- it is current practice among diving supervisors to use longer table times as a safety precaution in case of difficult

dive conditions. This procedure is clearly described in the U.S. Navy Manual which states that "if the diver was exceptionally cold, or if his work load was relatively strenuous, the next longer decompression schedule than the one he would normally follow should be selected."

With references such as the famous U.S. Navy Diving Manual, this statement became the corner stone of our approach to decompression tables validation. It provides:
- an ethical basis to the problem of sending new decompression procedures to worksites,
- a simple explanation for applying to government authorities for the permission to use the modified decompression procedures.

Instructions

Practically, the new tables were presented in a small manual edited as special instructions by the company methods department. The instructions were said to be designed for worksites associated with difficult dive conditions, i.e. cold, hard work, current, intensive diving operations, etc...

This procedure was aiming at avoiding questions of divers being exposed to different decompression instructions on different worksites.

Worksites

For obvious reasons, the new decompression procedures were sent only to pilot worksites. The following criteria were used for selection:
- favourable legal environment and good relations with the client permitting the introduction of special instructions without arduous discussions,
- proximity of the worksite or specially well organized operation base allowing a good feed back of information,
- high standards of professionalism among the LST's, diving supervisors and diving superintendents insuring that the new procedures were correctly understood and strictly followed,
- intense diving operations in the depths and times related to the new tables, providing a large volume of dive records.

As far as possible, the operational personnel (diving supervisor, LST's...) were briefed prior to being sent on the barges and interviewed upon their return onshore. Weekly contacts were made by telephone or radio. However, the main source of information was the dive reports.

Dive reports

The dive reports are part of the Comex internal reporting system and include three sorts of document:
- the diving report which contains the basic information on the dive parameters. It is primarily a working document used to keep a good record of all operations. It is also a contractual document between the diving contractor and the client, that serves to control the work performed. It is finally a legal requirement, the report being used as the only reference in case of emergency or accident.
- the chamber log which is filled in whenever a deck chamber is operated. It contains all the information relevant to ambient parameters controls, during normal dives, but also all details of the treatment in case of DCS.
- the accident report which is filled in for DCS cases.

Comex diving report, Chamber monitoring report and Accident report sheets are shown in appendices.

The Comex Data Bank

Whenever a dive is carried out on Comex worksites, a copy of the dive report is sent to the method department in Marseille (the reports have carbon copying sheets which are used for the dispatch, one for the worksite, one for the base and one for the method department).

All the reports received are fed into a computer. This computer system called the Comex data bank.

When typing the reports in, the computer runs automatic tests on the consistency of the data. Tests include, for instance, comparison of actual dive depth and time with table depth and time, check of the actual decompression time against correct decompression time, correspondence of dive depth with diving method and breathing gas, etc.. The reports are typed in by operational personnel, who are qualified to correct any abnormalities eventually detected.

In addition to the above precautions, the validity of the data is checked at worksite level. The local trends are compared to the general results to identify systematic errors of procedures or simply missing reports that would bias the statistics.

Objectives

Safety was the primary concern of the study.

Safety of the decompression tables was measured in term of number of DCS recorded. Any accident/incident/near misses not directly related to decompression procedures was rejected.

The accident reports were checked by the safety officer, the medical department and the method department. Complementary

information was eventually obtained by inquiry, interview, post accident medical examination, etc.

Efficiency was a second objective. A special effort was made to produce a manual with clear and simple instructions. Back up procedures were detailed for decompression emergencies such as exceeding the planned bottom time, impossibility to carry out the 3m stop due to worsening sea conditions, oxygen supply failure during oxygen stops, etc. Efficiency was measured from the comments of the project managers, diving superintendents and supervisors who learned to use the possibilities of the tables and reported on their practical and commercial consequences.

RESULTS

Operations

The validation of the new procedures took place from 1985 to 1986.
The instructions were sent to selected worksites around the world: shallow long tables tested in the Persian Gulf during welding operations not exceeding 24 msw; deep tables were implemented in Burundi, for the installation of fresh water lines for Bujumbura City; surface decompression tables used in North Sea inspection operations...

DISCUSSION

The method used to introduce the decompression table is not new. Even if the process is reluctantly admitted and rarely published, it is the simplest approach to improvement of decompression tables. Most of the diving contractors have used this empirical method to develop their own procedures from the original U.S. Navy Manual tables. Even at the worksite level, diving supervisors have for long developed similar recipes for the improvement of decompression safety. However, it is the first time that the method has been used systematically and presented as the only reasonable and practical way of developing new decompression tables.

Potential of the method

The primary limitation of the method is that it only provides improvement over former decompression tables and that there is no room for drastic change or new ideas. Using this method, we are bound to "Haldanian" decompression procedures forever! However, it must be recognized that the method allows for some innovation and that the work done for the new French tables has at least documented the fact that deeper stops are associated with safer decompression.

TABLE 1[a]

Dives recorded after two years of offshore evaluation of the new French Air decompression tables

Tables	Number of man x dives	Number of tables used
Air Std Standard	124	4
Air/oxy at 6m	814	55
Air/oxy at 12m	573	40
Air Surf D	627	52
TOTAL	2138	

[a]This table summarizes the results obtained in January 1987. An estimated number of 1,000 additional diving reports are still waiting to be treated by the computer.

The second limitation is that the method tends to produce non-optimal decompression schedules. As the basic assumption is to promote longer decompression, it is impossible to consider shortening decompression stops for schedules judged too conservative. In that case, information should be obtained from a complementary source. In fact, the problem arose with the 1974 French tables for the no-stop decompression limit which was considered too restrictive. To slightly extend no-stop limit, reference was made to the data published by the DOE on UK North Sea operations (2), which clearly documents that the U.S. Navy no-stop decompressions are very safe.

In any case, these short comings are well counter-balanced by the capacity of the method to produce large volumes of data and to allow statistical analysis of the results.

Time required

As Comex has an international activity, the possibilities to use the new tables were numerous. However, it took two years before sufficient information was gathered. The difficulties did not arise from legal or commercial constraints but rather out of the criteria for selection of the worksites. The list of worksites operating in the "interesting range," providing good feedback of information and control of procedures, appeared relatively short. It must be admitted that even for a large diving company, the process is slow.

Divers acceptance

Divers acceptance was good. The reason being that they are used to such modifications in case of difficult dive conditions and that they merely considered them as "Jesus factors." They even treated our new tables, which we consider as "la crème de la crème," as modified U.S. tables!

Quality of the information

The Comex system of computer processing of diving reports was set up in 1974. Similar systems are known to be run by the U.S. Navy (5), the Canadian forces (6) and the University of Pennsylvania, but until 1983 it was the only example of a data bank covering commercial diving operations. The only recent equivalent is the system presently commissioned by the DOE to Dr. Shields for North Sea diving operations.

Besides the volume of the information, the nature of the operations (military, scientific or commercial), what really characterizes a given data bank is the accuracy of its data. A lot of time and effort must be put in checking the quality of the information and the success depends on two conditions.

The first condition is to have the authority to impose the diving report system. Operational personnel just hate paper work and a lot of incentive is required to get good feed back of information. Governments have legal means of pressure, a diving company pays its personnel, but a university, for instance, seems helpless. At Comex, we used a combination of negative actions (angry notes to worksites, warnings, ...) and positive actions (personal listing of dive records, safety records, ...) until the system was recognized as useful for everybody.

cient diving form. The first diving reports designed by Comex looked like newspaper and they were far too complex to be efficient. In fact, a lot of information judged irrelevant or time consuming on the worksite was just not filled in. Several modifications of the report were proposed until we came to an acceptable compromise between what we would like to get and what diving supervisors would accept to fill in.

Started in 1974, the Comex data bank has been considered as reliable and fully operational since 1976. Results published (2) have shown to be in good accordance with other published statistics (1, 4, 5) and we believe that the system is a good and reliable tool.

Statistical analysis of the results

A large number of parameters are involved in the final safety performances of a set of decompression tables. The currently accepted independent parameters are listed in table no. 2. Because it is impossible to control all these parameters during a given dive, the outcome of the decompression table has been considered as a probabilistic event. Validation of a new set of decompression procedures thus requires recording many dives, performed by many divers, on many different worksites. This is for at least two reasons.

First, considering present commercial diving practice, the list of controlled parameters reduces to:
- dive technique (in-water or surface decompression),
- breathing mix,
- pre-dive surface interval,
- dive depth and time.

TABLE Nº 2

LIST OF CURRENTLY RECOGNIZED FACTORS INFLUENCING THE PERFORMANCE OF A DECOMPRESSION

DIVE CONDITIONS	ERRORS OF PROCEDURE	INTER INDIVIDUAL VARIABILITY	INTRA INDIVIDUAL VARIABILITY
- Water or chamber temperature	- Poor control of depth (swell)	- Training, Experience	- Fatigue after travelling
- Wet suit, dry suit, or hot water suit	- Wrong calibration of gauges	- Adaptation to narcosis	- Fatigue after intense diving
- Light or heavy work at bottom	- Error in calculation of bottom time	- Physical fitness	- Hangover, Flue
- Up and down depth variations	- Selection of wrong schedule	- Smoking, Drinking	- Anxiety, Stress
- Swell	- Omitted decompression stop	- Weight, fat content	
- Current	- Shortened decompression	- Age	
- Visibility	- Exceeding the surface interval	- Previous DCS history	
- Narcosis	- Leakage on oro-nasal mask		
- Dry/wet environment	- Wrong quality of oxygen		
	- CO_2 in breathing gas		
	- Work/exercise after decompression		

This means that the decompression tables must fit all the divers, for all the dive conditions and all the worksite procedures. Good training, adequate equipment and sound procedures may reduce the influence of the other uncontrolled factors but not eliminate them. It is therefore expected that any variations of these uncontrolled factors will remain within the safety margin of the decompression tables.

Statistically, this assumption is equivalent to considering the uncontrolled factors as random events of low incidence. Then, the overall combination of all these secondary variables has a random effect on the final result. Such an assumption requires that the number of dives studied is large enough for the secondary variables to be considered as centered, normal variables of small standard deviation (7). This is not always the case and we can recall a diver who twice got a DCS with the new table and who certainly introduced some bias in the evaluation of the new procedures.

Secondly, because of the random nature of DCS occurrence, it is necessary, when comparing the performance of different schedules, to implement statistical techniques (7, 8, 9, 10).
However, DCS incidence in commercial diving is low. Present state of the art in air decompression tables range from 0.5% to 2% of DCS occurrence depending on dive exposure (1, 2, 4, 5) and the classic statistic tools appear very inefficient in separating table performances. Using standard comparison technique for observed percentages, it requires about 100 dives without any accident to show any improvement over a former schedule which was used 25 times with 1 DCS occurrence! It might be even more drastic if one DCS is recorded during the evaluation of the new table.

The practical implication is that, nowadays, the number of dives required to document any significant improvement of new tables over the former ones is large.

Considering the 2,100 dive reports collected and the 1,000 dive reports waiting for processing, we can rely on an approximated 3,100 dives for this study. It might appear small when compared to the 60,000 dives recorded with the French 1974 tables, but it must be noted that:
- exposures recorded are located in the critical depth and time range.
- a given worksite generally operated at constant depth for almost always the same bottom time and the dives recorded are concentrated on small number of decompression schedules.

However, even though the process of data acquisition has lasted for two years, we must admit in 90 % of the cases, the information gathered was insufficient to allow conclusive comparison of table by table. As a consequence, when decompressions were insufficiently documented the results of several schedules were grouped together into categories to allow statistical comparison.

CONCLUSION

Even if the method developed is relatively limited and very slow, it appears to be a reasonable way of introducing new decompression tables because today, lengthy and tedious dive logging is required to document any modification of procedures.

Even though this study has represented an effort to implement statistical techniques, it is right to say that the exact tables performances will be only known in ten years from now, when tables will have been used as standard procedures and 100,000 dives will have been recorded!

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Funding support was provided by the FSH (Fonds de soutien des Hydrocarbures) by the CEPM (Comité des Etudes Pétrolières Marines). Fiche no 4723/83.

DIVE REPORT

N° .....

WORKSITE

Date Day ◂ Month ◂ 19 ◂

Surface Support .....

Location .....

Client / project .....

DIVE CONDITIONS

Current (Knt) ☐ <0,5 ☐ 0,5 - 1 ☐ >1

Swell (m) ☐ none ☐ 1-3 ☐ >3

Water visibility ☐ good ☐ poor ☐ none

Water temp. (°C) ☐ 0-10 ☐ 10-15 ☐ >15

BOTTOM MIX ☐ air ☐ nitrox ☐ heliox

Bottom mix analysis : Mix 1 .. % O_2

Mix 2 .. % O_2

PERSONNEL

Superintend.

Supervisor

Diver 1

Diver 2

Bellman

Stand by diver

LST supervisor

DIVERS EQUIPMENT

	Diver 1	Diver 2	Bellman
Suit	.....	.....	.....
Head gear	.....	.....	.....
Bail out	.....	.....	.....
Gas heater	☐	☐	☐
Gas reclaim	☐	☐	

ACCIDENT Supervisor's signature

☐ No ☐ Yes

SURFACE ORIENTATED DIVING

☐ SCUBA ☐ Surface demand

☐ Wet bell

DIVE

Diver Depth .. m

Diver start descent ..

Diver at bottom ..

Diver start ascent ..

Dive bottom time .. min

DECOMPRESSION

☐ Cx Air No Stop ☐ Cx Air Standard

☐ Cx Air/Oxy 6m ☐ Cx Air/Oxy 12m

☐ Cx Air Surf. Decomp. ☐ Cx Nitrox

☐ Cx Heliox ☐ Other

.....

Table depth .. m

Table Bottom time .. min

Table Surface Interval .. h ..

STOP	ARRIVAL	DURATION	GAS
36 m			
33 m			
30 m			
27 m			
24 m			
21 m			
18 m			
15 m			
12 m			
9 m			
6 m			
3 m			

Diver at surface ..

FOR SURFACE DECOMPRESSION

Diver leaves 9 m stop ..

Chamber at 12 m ..

Surface Interval .. min .. sec

Stop at 12 m .. min

Chamber at surface ..

BELL DIVING

☐ Bell bounce ☐ Bell atm dive

☐ Bell sat ☐ Sub lock out

DIVE

Diver depth .. m

Bell depth .. m

Storage depth .. m

Hub decomp ..

Start bell descent ..

Bell at bottom ..

Bell pressure up ..

Door opened ..

	Diver 1	Diver 2
out	..	..
in	..	..
out	..	..
in	..	..
Total time	..	..

Door closed ..

Start bell ascent ..

Start decomp. ..

Bell on deck ..

Hub pressure up ..

FOR BELL BOUNCE DIVE ONLY

Table used .....

Table depth .. m

Table bottom time .. min

End of decompression ..

WORK PERFORMED

☐ Construction ☐ Inspection

☐ Repair, Maintenance ☐ Welding

☐ Drilling assistance ☐ Other

.....

BELL PARAMETERS

Time									
P. Mix 1 bar									
P. Mix 2 bar									
PO_2 mbar									
PCO_2 mbar									
HW Temp. °C									
HW Flow l/min									

NOTE : All times should be taken from the same watch

TO BE RETURNED TO COMEX SERVICES - OPERATIONS DIVING - 36, Bd des Océans 13275 Marseille Cedex 9 - France

comex

CHAMBER MONITORING REPORT N° _____

DATE day ___ Month ___ 19 ___

Surface support

Location

SUPERINTENDENT

CHAMBER OPERATORS

PERSONNEL IN CHAMBER 1	PERSONNEL IN CHAMBER 2	PERSONNEL IN CHAMBER 3

TIME	DEPTH metres	OXYGEN						CO_2			HUMIDITY			TEMPERATURE			OBSERVATIONS AND FILTER CHANGES
		C1 %	C1 mb	C2 %	C2 mb	C3 %	C3 mb	C1 mb	C2 mb	C3 mb	C1 %	C2 %	C3 %	C1 °C	C2 °C	C3 °C	
h																	
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DISCUSSION FOLLOWING MR. IMBERT

DR. LAMBERTSEN: In evaluating these tables, did you utilize the previous information or did you only begin an entirely new study? It sounded as though you used the past to judge what to do and then you went on to do a testing of what you had done. Is that correct?

MR. IMBERT: Well, the study was organized in several steps. And one of the first steps was an evaluation of the 1974 French tables. We ran tests on dive logs during the last eight years. As for the new proposed tables, we studied special worksites. So, the second step only concerned specific worksites and 3,000 dives.

CHAIRMAN SCHREINER: This is a good example of what came out of our discussion yesterday, which is the linkage of a data base with operational and research information and the feed back loop that can help us incrementally advance decompression procedures.

STATISTICAL PRINCIPLES USING SMALL SAMPLES, AND A NEW APPROACH

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INTRODUCTION

Statistical evaluation of decompression responses can improve decompression table development and safety. Testing and validation of decompression tables involves several policy decisions that affect the choice of an appropriate experimental design. Policy decisions 1) restrict the testing of human subjects and 2) determine the level of acceptable risk from decompression sickness (DCS) represented in operational decompression tables.

Acceptable risk (1,2) plays an important role in the decision making process that shapes dive table development, validation and operational use. For example, at the development stage, it will constrain the pressure and duration of hyperbaric exposure to maintain an appropriately low level of DCS incidence. Acceptable DCS incidence will also vary with the user population. Sport, scientific, commercial and military diving populations have different levels of acceptable risk. Another complicating factor is the fact that DCS has three major manifestations: limb bends, CNS-DCS (mostly spinal cord) and the chokes (3). Each manifestation has a distinctly different underlying frequency distribution and each manifestation carries a different risk of morbidity.

Methods that quantify DCS incidence should employ an efficient testing program to minimize cost and effort. Such a testing and validation program will usually contain a model of DCS incidence to minimize the number of man-dive trials required in table validation procedures. Since this paper addresses the use of small samples in table validation, factors that directly affect small sample testing will receive most attention.

ACCEPTABLE LEVEL OF RISK

Sport, scientific, commercial and military divers may have different levels of acceptable DCS risk. Risk perceptions (4) and operational requirements will differ within these diver populations. This in turn will determine the level of acceptable DCS incidence in decompression procedures recommended to the intended user group. Secondly, human subjects being tested will often encounter a higher DCS risk during testing and validation programs than in the final tables (See the Lanphier and Bennett papers in this Workshop). Lastly, sport and scientific divers may be more susceptible to DCS than physically-fit military divers. These risk constraints will influence the experimental design of a decompression testing and validation program.

What risk will be assumed by a user population to achieve a level of benefit becomes a crucial factor that determines an acceptable level of DCS incidence. For the sport diver, the risk is voluntary, and, in this sense, it is similar to other voluntary activities such as hunting and skiing (5). While sport diving with compressed air is a voluntary activity that entails perceived risk, we believe that sport divers would generally choose dive tables virtually free of DCS risk. An acceptable DCS incidence in this population might range from 1/1000 (0.1%) to 1/10,000 (0.01%) per dive. Many sport divers who follow the U.S. Navy no-decompression air tables (6) routinely use *ad hoc* safety factors such as an additional shallow water decompression stop or less bottom time to achieve a lower DCS incidence. Sport divers use such stops to reduce DCS risk perceived to be too high in the standard air tables.

Most sport and scientific divers wish to achieve a virtually safe decompression, an example of a *virtually safe dose* as defined in risk assessment (7). While military and commercial divers may assume a higher DCS incidence than most sport divers, medical care and treatment

facilities are often more readily available for them than for the sport diver. Prompt medical treatment with recompression reduces the risk of permanent injury from DCS. Acceptable DCS incidence for military and commercial divers may be close to 1/100 (1%) or 1/1000 (0.1%). Legal questions that can arise over what is a significant risk (8) and other issues (See Sutterfield, this Workshop) can further complicate what is an acceptable risk.

RISK OF SERIOUS INJURY

At this point, a distinction should be made between the risk of serious injury and DCS incidence. DCS incidence is the combined incidence of limb bends, CNS-DCS and the chokes. While the levels of acceptable DCS incidence show differences according to operational use, only the relative frequency of certain DCS manifestations actually determine the risk of serious injury or death. Limb bends *per se* carries no risk of serious injury as compared to life-threatening spinal cord CNS-DCS and the chokes. Limb bends and CNS-DCS, mostly spinal cord injury, occur with different proportions in no-stop air dives (9), and the chokes appears uncommon. Since a higher proportion of spinal cord DCS injury occurs in relatively short, deep "bounce" dives (10), the risk of serious injury appears greater in short, deep dives than in long, shallow dives with the same DCS incidence.

Although we recognize that differences exist between morbidity from the various manifestations of DCS, the relationship between DCS manifestations and dive profile is not well understood. However, we consider any DCS manifestation undesirable. For these reasons and for the sake of simplicity, we will address procedures that evaluate DCS incidence in decompression procedures without directly assessing the underlying risks of serious injury and death.

GENERAL APPROACH TO EFFICIENT TESTING AND VALIDATION

What effect does the level of acceptable risk have upon testing and validation procedures? Answers to this question are difficult. Generally, as we lower acceptable risk, we must also increase the number of trials. We will point out some approaches that can reduce the number of trials needed. Appropriate statistical methods and additional sources of information can increase the efficiency of dive testing and validation. We will discuss statistical approaches that can enhance testing and validation when low DCS incidence estimates are sought.

Previous tests, DCS models and dive tables

Since the DCS incidence and serious injury risk should be low in the testing phase and in the final dive tables, we can use existing information on human decompression responses to evaluate regions of interest in a decompression procedure. Data from well-controlled human decompression experiments that fit the experimental testing design can provide additional information that would be costly to repeat. We can reduce the number of dive trials by evaluating decompression responses available in various data bases by DCS modelling (See Weathersby, this Workshop). Existing dive tables that have been thoroughly validated also contain information useful to formulate an experimental design for testing new tables.

Animal tests

Preliminary animal testing avoids unknown risks to human subjects and provides information about decompression responses where known risks are unacceptably high. Animals with about the same body weight as humans, such as the goats that Haldane and colleagues used so successfully (11), offer physiological models of human DCS. Decompression responses from these animals are generally similar to human responses and can be compared, based on body weight extrapolation, by a procedure known as allometric scaling (12).

Doppler bubble detection and decompression severity

The extent of bubble formation also contributes information about the overall severity of decompression. Doppler-detected bubbles afford a precursor index of decompression severity that complements the presence or absence of frank DCS episodes. Spencer and his colleagues (13) and a joint Canadian and French team (14)

demonstrated how Doppler bubble detection can be used to plot bubble scores that correspond to decompression severity. Nishi and associates (14) found a close fit between no-stop decompression limits of the Royal Navy air tables and their bubble scores. Although bubble detection among individuals with about a 10% DCS incidence has not proven to be so successful in distinguishing clinical DCS (15), studies with bubble detection indicate its potential value as an adjunct to DCS provocation (See Nishi and Eatock, this Workshop).

SINGLE DECOMPRESSION PROCEDURE TESTING

Now we wish to discuss testing of a single decompression procedure with one pressure and duration dive profile. To assess DCS incidence, the binomial distribution can be used. We will illustrate this procedure with a few examples. More generalized testing such as the validation of decompression schedules will be covered in the next section.

Homer and Weathersby (16) addressed the importance of placing decompression testing on a firm statistical basis. Human testing and validation trials of decompression tables have been conducted historically on an iterative basis by increasing or relaxing the severity of decompression insult until the investigators felt that a table or decompression procedure was safe. This was often done with a Haldanian model of DCS incidence based on gas tensions (11). However, the safety of such a table or decompression procedure was not explicit. Statistical techniques now available offer a means for explicitly estimating how safe the dive tables really are.

Binomial probability

Binomial probability is treated in most introductory statistical textbooks. Zar (17) presents a lucid description together with a table of proportions of the binomial distribution up to a sample size of 25. The binomial distribution permits the investigator to calculate the exact probability of binary events, e.g. the presence or absence of DCS. This method can then be used to estimate how many dives would be required to test a single decompression procedure as shown by Homer and Weathersby (16). Fortunately, computing binomial probabilities is fairly straightforward whether by hand calculator (Appendix) or by statistical computer programs, such as Minitab (18).

Rejection rules with binomial probability

If we want to know the probability of rejecting a decompression schedule, we can take the Homer and Weathersby approach (16). They compute the probability of rejecting a table against a "true" incidence of DCS using 10, 20 and 40 successive man-dives with at least one DCS case as the rejection criterion. The procedure involves testing a single dive profile. As the number of fixed trials increases, the probability of rejecting a

Table 1. Expected percentage of trials with DCS cases from randomly sampled 1, 5 and 10% underlying DCS incidence

Dives/ Trial	DCS Cases	% DCS Incidence 1	5	10
5	0	95.1	77.4	59.0
	1	4.8	20.4	32.8
	≥2	0.1	2.3	8.1
10	0	90.4	59.9	34.9
	1	9.1	31.5	38.7
	≥2	0.4	8.6	26.4
20	0	81.8	35.8	12.2
	1	16.5	37.7	27.0
	≥2	1.7	26.4	60.8
50	0	60.5	7.7	0.5
	1	30.6	20.2	2.9
	≥2	8.9	72.1	96.6

"risky" schedule increases. They show that even at a 10% incidence (0.1 probability of the bends), only the 40 dive trial is a sufficient test to uncover a risky schedule with a 10% DCS incidence more than 90more than one% of the time. Looking at a lower, but still usually unacceptable DCS incidence, rejection becomes more difficult. At a 4% incidence of DCS, a trial of 40 dives will reject the decompression schedule somewhat more than 80% of the time. In this second example, the rejection rule calls for almost a one in five acceptance of a comparatively risky dive table after 40 man-dives free of DCS.

Expected percentage of trials with DCS

To further illustrate the above points, we show likely randomized trials having different DCS incidence. Table 1 contains an example with 5, 10, 20 and 50 dives per trial. We calculated with binomial probability the percentage of trials with 0, 1 and 2 or more DCS cases from underlying DCS incidence of 1, 5 and 10%.

To illustrate the fact that no DCS may be observed even at incidences which are generally unacceptable, we note that the percentage of trials that provoke no DCS with an underlying 5% DCS incidence drops substantially only between 20 and 50 man-dives per trial. Even a 5% DCS incidence with 20 man-dives will have more than 35.8% of the trials without DCS.

Table 2. Percentage rejection rate of dive schedules with 0.1, 1 and 10% DCS

No. of Dives	No. of DCS Cases to Reject	% DCS Incidence 0.1	1	10
10	1	1.0	9.6	65.1
	2	0.004	0.4	26.4
20	1	2.0	18.2	87.8
	2	0.02	1.7	60.8
50	1	4.9	39.5	99.5
	2	0.12	8.9	96.6

Percentage rejection rate

A table such as Table 1 can be used to obtain the probability of rejecting a dive table for a given rule. Such probabilities are given more explicitly in Table 2. With 1 or 2 DCS cases to reject a 10% DCS procedure, 95% rejection of a dive profile occurs only between 20 and 50 man-dive trials.

Table 3. Percentage acceptance rate of dive schedules with 0.1, 1 and 10% DCS

Number of Dives	Number of DCS Cases to Accept	% DCS Incidence 0.1	1	10
10	0	99.0	90.4	34.9
	≤1	99.996	99.6	73.6
20	0	98.0	81.8	12.2
	≤1	99.98	98.3	39.2
50	0	95.1	60.5	0.5

In statistics, there is a duality or trade-off between accepting a risky table and rejecting a safe table. If a 0.1% DCS incidence level occurs, a 50 man-dive trial with a one DCS case rule will reject this "safe" decompression schedule in almost 5% of the trials. We can improve this by relaxing the rejection requirements. For two DCS cases rejection with 50 dives, the rejection rate with a 0.1% DCS incidence dive schedule drops to 0.12%. However, the probability of rejecting an unsafe table will have also been reduced. The only way to improve overall performance is to further increase n, the number of dives in a trial.

Percentage acceptance rate

Another way to present these results is by focusing on the acceptance rate of low risk and high risk decompression procedures (Table 3).

Acceptance rate is simply 100% less the previous percentages given in Table 2 and represents the other side of the coin. In this example, the maximum number of DCS cases for dive schedule acceptance is one less than the number of cases to reject a dive schedule. Both tables compare what statisticians refer to as Type I and Type II errors with an inappropriate rejection or acceptance of a decompression procedure.

Binomial confidence limits

Confidence limits for a binomial distribution with a fixed number of trials and underlying incidence can be calculated or determined on an inexpensive slide rule (TEAM Corp., Tamworth, NH 03886). Charts of 95 and 99% confidence intervals are also available in a book by Box, Hunter and Hunter (19). Tabulated confidence intervals appear in a book by Snedecor and Cochran (20) that cites Crow (21). These are so-called "exact" confidence intervals. Often used normal approximation of the binomial confidence interval becomes increasingly susceptible to error when proportions (DCS percentages) are low and sample sizes are less than 50 (20).

Binomial confidence limits illustrate the relatively large numbers of trials needed to determine, within reasonably narrow 95% confidence limits, the incidence of events that occur with low probability (< 5% DCS incidence). In table testing and validation, we are most concerned with low incidence probabilities. Confidence limits are typically broad, particularly with small samples, and this fact again points to the statistical difficulties implicit in dive table testing and validation.

MODEL FITTING

Another approach can offer greater efficiency in statistical testing and validation. This section focusses more on experimental the phase rather than the validation phase of dive table development. One can test decompression procedures with a small number (about 3 or 4) similar pressure and duration combinations. Rather than relying on a test of one profile, this method can be used to acquire information on decompression responses from *similar* decompression profiles of interest. Such an approach can gain efficiency by reducing the number of trials necessary to test or to validate a set of *similar* dive schedules. This approach is not constrained by successively testing single dive profiles one at a time. Information from single dive profiles can be tested as before, but data from individual profiles can also be pooled and again tested with a more general model of DCS incidence.

At this point, some aspects that influence decompression schedule testing and validation should be summarized.

1. Decompression responses are not well understood. We are only now coming to realize that the relative proportions of DCS manifestations depend on the dive profile. Morbidity risks vary with the form of DCS.

2. Rare event estimation is not easy. The examples provided in the above review of binomial probability indicate some of the difficulties and the need for an optimization of the table testing and validation procedures.

Although DCS modelling is not the primary topic of this paper, its use appears essential if dive table testing is to be conducted in the most cost effective way. If some reasonably correct assumptions and predictions about the behavior of DCS incidence with pressure and dive duration can be made, then decompression responses can be pooled, and testing becomes more efficient.

Dose response curve approach

Essentially, dive schedule testing is similar to the dose-response methods used in bioassay. These are described in a rich statistical and pharmacological literature, e.g. Finney's books (22,23). However, some important differences exist between conventional bioassay techniques at high incidence levels and rare event estimation at < 1

to 0.1% incidence typical in table validation. Low incidence levels challenge the statistician to provide reasonably good DCS incidence estimates without demanding too many dives.

As previously mentioned, decompression testing is in many ways similar to the usual approach taken in dose response curve fitting used by Finney (22,23) in bioassay. While reliability testing to estimate equipment failure often deals with rare events, the methods used are not directly applicable to the problems encountered in table testing and validation. Induction of DCS in a diver appears more analogous to drug testing. In drug and dive schedule testing, each involves testing a set of doses to determine whether they produce a physiological effect. In dive table testing, safer decompression procedures are achieved usually by decreasing the decompression "dose" by reducing decompression rate, bottom time, or the maximum exposure pressure.

Model dependence of low probability estimates

DCS incidence estimation from binary (or quantal) responses becomes increasingly model dependent, particularly at low probability levels, <5% . We have observed that the frequency of DCS appears to rise sigmoidally with the severity of decompression insult. One can evaluate DCS incidence by using a distribution that accounts for the S-shaped decompression response. Finney (23) compares some commonly used distributions, including the logistic distribution that we have successfully used in our DCS studies. At a DCS incidence less than about 5%, Finney's illustration (Fig. 17.14.1, ref 23) shows considerable divergence between some of the models, although the normal and logistic distributions remain quite similar. At this time, we do not know enough about the behavior of low DCS incidence to recommend a particular distribution, although the logistic distribution provides a reasonably good fit for modelling DCS as a function of log pressure and log duration based on our experience.

DCS estimation

Cox (24) and Hubert (25) provide statistical methods for the analysis of bioassay data that find application in table testing. Hubert shows an explicit calculation of the standard error of dose corresponding to a given incidence. Standard errors can then be used to calculate confidence intervals. Several statistical packages, such as SAS (26), provide statistical algorithms for the "dose" corresponding to incidence. The SAS routine also gives 95% confidence intervals for the "dose," which in this case is log bottom time or log pressure. In our decompression studies referred to above, we have assumed a logistic distribution of DCS events. The models were fit by the GLIM statistical package (27).

An example of human decompression responses serves to illustrate the estimation of DCS incidence based on no-stop decompressions conducted with compressed air (Fig. 1).

DCS incidence estimates were computed with GLIM as previously described. The left side of this graph contains DCS incidence estimates derived from the Van der Aue *et al.* (28) sea trial data. DCS estimates, seen on the right side of this graph, represent Behnke's data (29) from chamber dives. These DCS incidence estimates, represented by effective dose (ED) isopleths that span dive duration in the respective data sets, closely match the DCS incidence thought to occur when the U.S. Navy (6) and the Royal Navy (30) no-stop air tables are followed out to their limits.

Efficient sequential designs

Table development often involves an iterative approach to achieve "safe" decompression procedures. This testing phase is usually followed by a validation phase before dive tables are introduced for operational use. Our attention in this section is directed at optimizing the testing phase.

Methods used to estimate the dose associated with a given probability of quantal or binary responses are reviewed in a paper by Wu (31). He recommends a design that incorporates an estimation procedure that chooses the next dose to test based on the observations collected.

In our work, we found a modified iterative approach to be an effective strategy for determining "dose" levels of decompression. Each successive trial tested a decompression procedure at three levels of decompression severity, each represented by a small number of animal-dives (<20). Responses were evaluated and more "dose" levels were added when necessary so that we

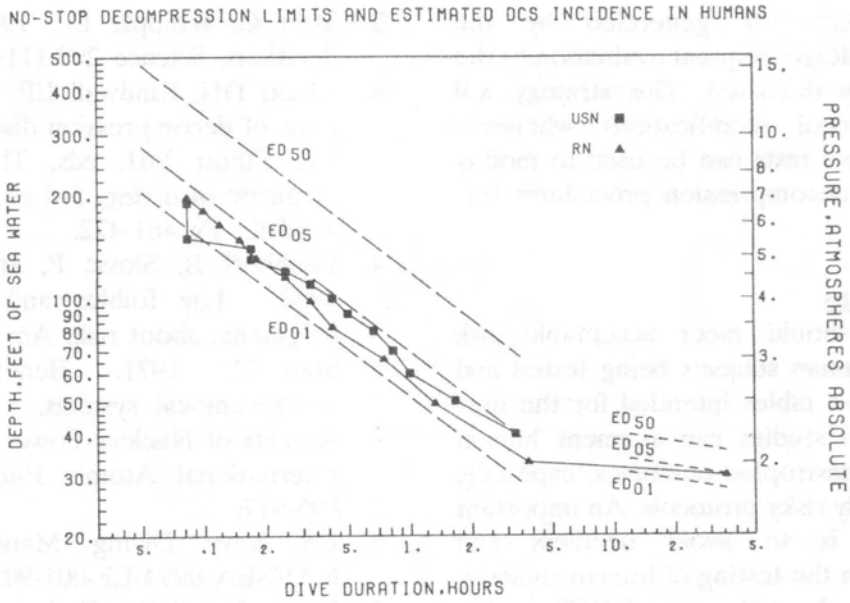

Figure 1. Comparison between no-stop decompression limits in the U.S. Navy (USN) and Royal Navy (RN) air tables versus DCS incidence estimates derived from Van der Aue and associates (28) and Behnke (29) decompression trials.

quickly found "dose" levels that provoked an appropriate DCS incidence. We call this procedure sequential iterative testing.

We find this procedure particularly useful in pilot studies for selecting dive profiles. If a certain profile does not provoke DCS, another slightly more severe may. Some DCS becomes more likely because the testing protocol is not rigidly confined to a single decompression profile. This procedure enables the investigator to alter the protocol more readily and to acquire more decompression responses closer to the desired DCS incidence level. Indeed, this approach closely follows some of the empirical methods applied in the early testing by the U.S. Navy.

However, this testing approach may also increase the number of DCS cases and this aspect may or may not be acceptable in the context of human subject risk. For this reason, DCS precursors, such as venous bubbles, can assume increasing importance in the testing and validation of dive tables.

RECOMMENDED APPROACHES IN TESTING AND VALIDATION

Single dive table validation

For the validation of a single schedule or table, we suggest a binomial probability procedure, similar to the approach described by Homer and Weathersby, with a sufficient number of dives to detect DCS at a level acceptable in the intended user populations. Sport and scientific divers require dive tables with an extremely low DCS incidence. Commercial and military may be willing to accept a higher risk based on operational considerations that include adequate bottom time for work and ready access to medical treatment with recompression.

Multiple dive table Testing and validation

For multiple table testing, we suggest an approach with trials that require three or perhaps four closely spaced levels of decompression insult in each trial. Each "dose" might be tested five or ten times. Decompression responses, either from the human testing or from past experience, can be used to estimate DCS incidence and to select the appropriate decompression insult.

Decompression responses generated by the protocol should undergo frequent evaluation by the methods previously discussed. This strategy will provide for protocol modifications whenever necessary. Successive tests can be used to modify or to validate the decompression procedures further.

Other considerations

Successive trials should meet acceptable risk requirements in human subjects being tested and in the validated dive tables intended for the user population. Animal studies can augment human testing to avoid catastrophic outcomes, especially in testing potentially risky protocols. An important ethical principle is to avoid needless and unacceptable risk in the testing of human subjects. Earlier suggestions about the use of DCS modelling, existing data bases of human decompression responses, bubble monitoring, and animal responses to decompression have obvious value for avoiding unnecessary human decompression trials.

IMPLICATIONS

We conclude this discussion with some implications drawn from the need for additional dive table testing and validation.

1. Sport and scientific divers need decompression procedures that achieve a lower DCS than now provided in the U.S. Navy no-stop air tables when carried to their limits.
2. Statistical testing and modelling decompression tables can quantify risk, enhance testing efficiency, and improve diving safety.
3. Acceptable decompression procedures with low risk create testing problems due to sample size requirements. Statistical approaches, similar to bioassay methods, can be used to optimize the testing and validation of decompression tables.

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APPENDIX: CALCULATION OF BINOMIAL PROBABILITIES

Binomial probability can be used to calculate several statistical measures of decompression schedule trials. The frequency of DCS cases in a given trial will indicate the underlying DCS incidence. Larger trials will provide better estimates of DCS incidence associated with a particular decompression schedule. The probability of various levels of DCS incidence can be estimated for trials that produce no DCS, 1 case, and 2 or more DCS cases (Table 1). Validation or testing rules offer a statistical method for rejecting (Table 2) or accepting (Table 3) a decompression schedule. Computation of binomial probabilities with a hand calculator or a statistical program requires computation of powers taken to the number of dives in a testing or validation trial. Tables of binomial proportions or access to computer-generated proportions are useful. For an illustration of binomial probability calculation, we chose several examples taken from Tables 1 and 2. In Table 1, the expected percentage of trials with DCS cases taken from 1, 5 and 10% incidence can be evaluated two ways.

Use of binomial proportions in tables

For a 20 dive trial with a 1% DCS incidence, the expected percentage of trials with 0, 1 and 2 or more DCS cases can be computed with a table of binomial proportions as found in Zar (17).

Problem: What is the expected percentage of trial series with 20 man-dive decompressions each and an underlying 1% DCS incidence that will provoke no DCS cases?

Solution: One can read the proportion (or probability) of 0 events (0 cases of DCS) directly from Zar's table as the proportion for a sample size (n) equal to 20. The proportion and probability equals 0.81791, and the percentage of 20-dive trial series without DCS is 81.8%.

Problem: What is the expected percentage of trials with 1 DCS case (as above)?

Solution: The proportion is 0.16523, and the percentage is 16.5%. Note that the remaining proportion of trials with 2 or more DCS cases is: 1 - (0.81791 + 0.16523) = 0.01686, or 1.7%. The sum of the proportions of all trials equals 1 (or all events = 100%).

Calculation of proportions
from binomial probability

Zar (17) discusses computing binomial probabilities. An example from Tables 1-2 illustrates the computation.

Problem: What is the expected probability of no DCS cases produced from an underlying 1% DCS incidence after 20 man-dives?

Solution: The probability of a random sample of size n containing x individuals in one category (i.e. no DCS) and n-x individuals in the other category (i.e. with DCS) is:

$$P(x) = [n!/x!(n-x)!][p^x q^{(n-x)}].$$

In this example, n = 20 dives in the trial and x = 0 DCS cases. Small p is the underlying DCS incidence, 0.01 ,and 1 - p = q. (Factorials are used to compute the probability, where

$$a! = (a)(a-1)(a-2)...(2)(1).$$

Thus, 5! is (5)(4)(3)(2)(1) and equals 120. Furthermore, 0! is defined as 1, and any number taken to the 0 power, n^0, is 1.)

$$P(x) = [20!/0!(20-0)!][(0.01^0)(0.99^{20-0})]$$

$$= [20!/0!20!][(0.01^0)(0.99^{20-0})]$$

$$= [1][(1)(0.99^{20})] = 0.81791.$$

Thus, P(x), with x = 0 for no DCS cases, equals 0.81791 or 81.791% of the 20 man-dive trial series that will contain no DCS.

Problem: What is the probability of 20 man-dive trials with 2 or more cases of DCS?

Solution: We know that P(0) = 0.81791. We need to know the probability of P(1), the probability of 20 man-dive trials with a single case of DCS. With both P(0) and P(1), we can determine what the remaining probability will be for trials with 2 or more DCS cases by subtraction:

$$P(\geq 2) = 1 - (P(0) + P(1))$$

$$P(1) = [20!/1!(20-1)!][(0.01^1)(0.99^{(20-1)})]$$

$$= [20!/1!19!][(0.01^1)(0.99^{19})]$$

$$= [20][(0.01)(0.8261686)]$$

$$= 0.1652337 \text{ or } 0.16523 \text{ when rounded.}$$

This is 16.523% of the trials. The probability of two or more DCS cases is:

$$P(\geq 2) = 1 - (P(0) + P(1))$$

$$= 1 - (0.81791 + 0.16523)$$

$$= 0.01686,$$

or 1.7% of 20 man-dive trial series with a 1% underlying DCS incidence will contain two or more DCS cases (Table 2).

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DISCUSSION FOLLOWING DR. LEHNER

DR. HAMILTON: I am going to be brutal here and ask does your paper contain equations or something that somebody else can pick up and use? If I have 1 hit out of 25 dives, how can I present this statistically? Are you able to recommend to us how to do it?

DR. LEHNER: I would recommend a procedure using sequential iterative testing with a small number of samples, getting some estimates, and based upon those estimates of DCS incidence--if you are in a new area--using those estimates to extend this testing approach even further.

From the standpoint of testing, I think it is really essential for most of us, including myself, to be able to collaborate with a statistician who has had some training in human subject testing, if possible. I know that may be difficult. In our setting, it is an extremely valuable experience to be able to interact with a statistician and analyze data that are produced from a particular series of trials.

DR. HAMILTON: But we all generate the same kind of data.

DR. LEHNER: I can not give you an explicit answer to that because it matters so much what you are finding in any particular schedule, how risky that particular schedule is from the standpoint of whether or not it would be producing a high incidence of serious DCS as opposed to pain-only bends. I know I am hedging.

REV. LANPHIER: Giving you reality, though.

DR. LEHNER: Reality, well, I think the situation is that we have to be very, very careful.

DR. HAMILTON: Can you come up with something that will help us do statistics on small numbers of decompression trials?

DR. LEHNER: Binomial probability offers a method for testing or validating a table with a single profile. The Wu paper presents a method of sequential testing, where you can choose the next dose in a series of dose trials.

DR. LAMBERTSEN: Two comments. First of all, I think there are two ways of developing tables. It sounds as though you are describing starting from scratch with no information at all, and then, of course, step-by-step, iterative activity is essential.

The second comment has to do with the use of animals, to make sure that you were not doing something very foolish. That sounds like a non-iterative approach and the animal work is not really bearing upon the behavior of the human. For animal work to be meaningful, we would have to be examining extreme circumstances, big steps, not iterative, controlled shorter steps that were based upon prior human experimentation.

What, specifically, would be the approach to doing the improvement upon all the work that has been done so far in all, of the different efforts that have been made so far? Are you suggesting that one needs animal work to produce the improvement in the decompression tables that we are looking towards?

DR. LEHNER: I suppose it depends upon the table you are talking about.

DR. LAMBERTSEN: Are you talking about big steps that you are going to try to make or are you talking about little ones? If you are talking about little ones, animal work is not going to help you determine whether a small iterative process is going to work. It would only determine whether something drastically different from what is going on now would work.

DR. LEHNER: Your first question I think spoke to the use of preexisting information with regard to human decompression responses. And that, obviously, requires the use of what human DCS data bases are available, such as the one at your

institution. I think it is extremely important that we do not repeat experiments that have been well controlled and done in the past. There is no necessity for doing that. It would be a waste of human resources not to avail ourselves of the human decompression data that already exists.

Animal responses are obviously interesting from the standpoint of what you spoke to; that is, looking at the large steps. And we can conduct experiments with animals that we simply cannot ethically do with humans. That is one of the great advantages of animal experimentation.

DR. YOUNGBLOOD: I want to recognize the benefits of this, and one very simple lesson that we all admitted in the past. I know I did and I think perhaps Peter [Bennett] did and maybe Bill [Hamilton] did, too, and that is to find a friendly statistician who speaks English.

The second thing is, I feel a little emotional resistance here in saying, "You must tell us how to get the data we want out of a small group of subjects." They may be telling us that that is impossible and we just do not like to hear it.

CAPT THALMANN: There is a difference between validating a model and validating a table, that is the conflict. If you are validating a model, you need decompression sickness in order to know where you are. If you are validating a table, your end-point is you do not want any decompression sickness.

We had a statistician come in and look at the O_2 toxicity data that we generated at EDU, and he looked at it and said, "Your problem is you are not convulsing enough people." That is exactly what you want to hear, but we were faced with the same problem that you were; we had a small number of data points and we asked him, "Can we make any sense out of it?" And he said, "No, unless you get more data points."

So, in table validation, you are working down near the zero incidence of the curve, whereas in a drug evaluation or anything else, you want to be up on the slope part of the dose-response curve so you know where you are. The people developing the tables want to validate the model because they want to know if their premises work, whereas the contractors do not care if the premises work, they just do not want to bend anybody.

So, when you come up with criteria, you really have to be careful that if you start to talk about *table* validation you do not slide into *model* validation, and that you differentiate between the two because the processes are different. You use different end-points for them.

CHAIRMAN SCHREINER: The purpose of having Dr. Lehner and Dr. Weathersby here today is to open up the dialogue. It needs to be opened up between those who gather data and those who know how to get the most out of data, and particularly with those who know how to make sure that before you gather data that your experimental design maximizes the return on the investment in terms of information.

ETHICAL ASPECTS OF VALIDATION

The Rev. Edward H. Lanphier, M.D.

The University of Wisconsin - Madison

Paradox: Why "ethics"?

Before doing anything else, I'd like to face a question that probably occurs to most of you. Why do we have to go through some "ethical" fandango in order to validate a decompression procedure that is almost certainly better than what we had before? After all, divers in the field are being decompressed according to bad tables modified by some master diver's "Jesus factors" and other questionable ideas...

This kind of situation is not unusual in medicine or elsewhere. For example, a barely-qualified practitioner can apply almost any medical procedure that comes into his head and will learn nothing in the process. Meanwhile, a controlled scientific comparison of treatments may almost be stymied by requirements imposed in the name of ethics (1).

We can thank the Nazis for the ethical hurdles. When their incredible misdeeds in the name of "medical research" came to light, the need for some kind of rules became obvious. At the same time, honest investigators realized that rules were needed to protect patients and normal volunteers even in good places in the USA.

It took a while for things like the Declaration of Helsinki (2) to crystallize, and the time-lag allowed me to enjoy a colorful career as a human subject. I wouldn't have had it otherwise at the time, but reminiscing about my experiences as a graduate student and postdoctoral fellow makes me thankful that I survived more or less intact.

Things weren't much better when I moved on to the US Navy Experimental Diving Unit in 1951. I was a medical officer by then, but I knew that my manhood would be questioned if I didn't participate in our table testing and oxygen tolerance studies. Besides, the only assurance the enlisted subjects had was that officers like me were willing to undergo the trials. Bends and convulsions were not infrequent at EDU in the days when men were men.

The University picture

Things have certainly changed, at least in medical schools and universities. One of my assignments here is to describe the prospect of table-testing in that setting. I did a lot of groundwork on that topic, but I got the best insights out of a long talk with Norman Fost, M.D., M.P.H. He is a professor of Pediatrics, head of the UW program in Medical Ethics, and an internationally-respected ***ethicist*** - a term that didn't exist not so long ago.

The real turning point in this matter was passage of the National Research Act of 1974. This Federal law requires all institutions that receive funds from the Department of Health and Human Services, usually through the National Institutes of Health (NIH), to meet rather stringent requirements.

The requirements are centered in what is called an ***Institutional Review Board*** or ***IRB***. Our IRB at the University of Wisconsin is called ***The Committee for Protection of Human Subjects in Research***. Authority for specifying and monitoring requirements is centered in the ***Office for Protection from Research Risks (OPRR)***, and the "bible" is OPRR's manual of regulations on human subjects (3).

OPRR: Protection of Human Subjects.

Strictly speaking, the law applies only to funding that comes from the Department of Health and Human Services, the parent of NIH. However, every institution - to qualify for such funds - has had to provide an ***assurance*** that describes its IRB and also "...principles governing the institution in the discharge of its responsibilities for ***protecting the rights and welfare*** of human subjects of research conducted at or sponsored by the institution ***regardless of source of funding.*** As a result of this requirement, I doubt that there is any university, medical school, or major hospital now that does not apply the same standards to all human studies across the board, no matter where the money comes from.

"Protecting the rights and welfare of human subjects" is the name of the game. You might say that this reflects the fact that we assume a special kind of responsibility for people when we do things to them, in the name of research, that might not happen in the normal course of events or jobs or treatment.

In the years since 1974, the NIH approach has set a powerful precedent for work with humans anywhere. We might be able to do our table testing in some diving company or in an obscure private laboratory that has no NIH grants and would leave the "rights and welfare" worries to us. But it looks as if any end-run of that sort

would be foolhardy. In today's litigious atmosphere, deviation from accepted standards would almost certainly be illuminated sooner or later at great expense to somebody. It seems far better to do what needs to be done, either in the laboratory ***or in the field***, under the aegis of a good IRB.

What is an IRB, and what does it do? The specifications are remarkably detailed. For example, the OPRR regulations cover not only the size and makeup of the Board but many things about functions, standards, records, etc. -- as well as the ***assurance*** that I've already mentioned. This quote from the section on composition of the IRB seems especially applicable to our interests: *An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB..."*

Many IRB's would call in an outside consultant to help evaluate a proposal in diving medicine. In fact, I would want ours to do so. Otherwise, they would just be taking my word and Charlie Lehner's. That puts too much of a legal burden on us even if the IRB were satisfied.

Functions of the IRB are covered in considerable detail in the OPRR document (3). First of all, the IRB shall review all research activities covered by the regulations (and that would certainly include us). It has the authority to approve, disapprove, or require modifications in all such activities.

Criteria for IRB approval of research. Here are some of the criteria listed in paragraph 46.111:

(1) Risks to subjects are minimized. I must skip details, but this section reminds me to say that a good IRB can be a real asset and deserves to be approached accordingly. It can not only help keep you out of trouble but may actually improve your protocol.

(2) Risks are reasonable in relation to anticipated benefits...and the importance of the knowledge that may reasonably be expected to result. This is sometimes called the risk/benefit ratio. A poorly-designed study is inescapably ***unethical*** because the likelihood of benefit is not at all sufficient to offset any risk whatsoever.

Dr. Fost gave us a particularly interesting discussion under the heading of ***paternalism***. IRB's may differ considerably from one to another, and this is one point on which there is apt to be a lot of difference. A very paternalistic IRB is one which severely restricts the degree of risk to which subjects can be exposed. At the opposite extreme, an IRB may ok almost anything a subject is willing to do so long as he really knows what he's getting into. Most IRB's in the US apparently think that protecting subjects ***too much*** amounts to interfering with their rights and opportunities.

In England and France, normal subjects have been almost unprotected; but now that there have been some deaths and serious abuses (4,5), the pendulum is headed toward heavy paternalism (6,7).

Dr. Fost described our IRB at Wisconsin as being relatively paternalistic, but he did not think we would have trouble obtaining approval of a well-designed table-testing project. We had presented him with a plausible "test case" with an honest description of the risks as we see them. We did not claim that prompt treatment of DCS would necessarily rule out permanent injury. Even so, Fost felt that the Committee would consider our risks no greater than those that many people run in the ordinary course of their lives and work.

A good IRB will be interested in many aspects of subject safety, so our proposal to the IRB should show careful attention to everything that is relevant in that line.

(3) Selection of subjects is equitable. The guidelines here are not very detailed, but we might be asked under this heading whether it is appropriate to use students as subjects unless, perhaps, they are also divers. There are good reasons, ethical and otherwise, for drawing subjects from the population for which a procedure is intended. Any subject will be accepting risks, but trained divers should be better able to appreciate the risk and give more-fully-informed consent.

One of my assignments here is to "contrast the ethical situation of the laboratory subject with that of the diver who would use the new procedures." If I understand the underlying question, perhaps it would help to assume that what we do in the laboratory will identify problems with a procedure and lead to its improvement. This would result in a safer procedure for the actual user. The laboratory subject is presumably taking a greater basic risk but doing so with greater safeguards. In the final analysis, the "ethical situations" of the laboratory subject and the diver in the field should be much the same.

If the intended users will include female divers, then women should be among the subjects. The proportion of women should eventually be large enough for us to learn whether their responses differ significantly or not. It clearly will not be practical to test fit vs unfit, young vs old, etc.; so kind of a mixed bag of subjects may be better than, say, all varsity

athletes or all "normal" undergraduates.

Most IRB's want to know how and how much you plan to pay your subjects. According to Dr. Fost, the basic rule is that you pay what you must to get the subjects you need. It is all right to pay someone for taking a risk. But there are limits. The inducement must not be such as to overwhelm a person's judgement. That could be equivalent to coercion.

This is a good place to suggest that we keep an eye open for subjects who have bizarre motivation for volunteering. They are rare (8,9), but they can cause serious problems.

(4),(5) Informed consent is next on the list. It must be obtained and documented. Details will be discussed presently.

(6) This item concerns monitoring the data collected to insure the safety of subjects. Here, the IRB would probably want to know how experience early in testing would be used to modify the table or procedure as we went on. Fair enough.

(7) Here, provisions to protect the privacy of subjects and to maintain the confidentiality of data are taken up. There is one section that I should quote: "Where some or all of the subjects are likely to be vulnerable to coercion or undue influence...appropriate additional safeguards (must) have been included in the study to protect the rights and welfare of these subjects." This topic also comes up under Informed Consent.

Informed Consent.

Paragraph 46.116, General requirements of informed consent, is especially important for us. The consent must not only be informed but also free of undue inducement or pressure.

All of this brings back memories of my own career as a human subject. I wouldn't have missed any of it - except maybe one or two things - but I thought of the chairmen and other mentors I was appropriately eager to please -- and who would not have been happy if I'd refused. I looked back at the Experimental Diving Unit, where one's manhood, team spirit, loyalty, and patriotism were certainly at issue along with the hazardous duty pay. In a military laboratory, there may have to be some special provisions (10). Dr. Fost reminded me that the use of prisoners for medical research is now entirely illegal for just such reasons (11,12).

Incidentally, we must be alert in ***any*** setting to the possibility that personnel may try to protect themselves and each other by modifying procedures without the investigator's knowledge, reporting or feigning symptoms that did not actually occur, etc. Such things have happened.

The OPRR document contains some very good material. In the introductory part, it says, "...no investigator may involve a human being as a subject in research...unless the investigator has obtained the ***legally effective*** informed consent of the subject...***sufficient opportunity*** to consider...minimize the possibility of ***coercion or undue influence***...language ***understandable*** to the subject...

Some IRB's would require a witness who would actually question the subject to ensure understanding. Written information of impractical length and pressure to sign without time to read could certainly invalidate the process.

Another good point: "No informed consent ...may include any ***exculpatory language*** through which the subject...is made to waive or appear to waive any...legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence."

Required information.

Under Basic elements of informed consent, this sections says, "...the following information shall be provided to each subject:" (I must reduce each section to a few words and emphasize only what seems exceptionally important.)

(1) That the study involves ***research***; its purposes, duration, procedures, and ***which procedures are experimental.***

(2) A description of any reasonably foreseeable risks or discomforts... (and this does have to be realistic and complete!)

This one is exceptionally important:

(6) "For research involving more than minimal risk, an explanation as to whether any compensation...and any medical treatments are available if injury occurs...

There is a fat folder in my files containing material that dates back at least to 1963. It is labeled "Insurance Problem," and it documents my efforts to get some kind of coverage for human subjects to take care of them in the event of injury: so they could be compensated without having to go to court and prove negligence. There have been three national commissions on this subject since I started worrying about it. All recommended some kind of national program to provide compensation, but there is still no such thing. The government hasn't provided anything... No insurance company will touch it.

As a result, our IRB requires us to in-

clude in the informed consent document a grim chunk of prose called the "non-compensation clause." In effect, it tells the prospective subject that if anything bad happens, that's tough. Actually, I'm sure some free medical care would be provided, but we can't even hint at that.

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and finally,

(8) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject *may discontinue participation at any time* without penalty or loss of benefits...

Additional elements of informed consent.

When appropriate, one or more of the following elements of information shall be provided to each subject:

(1) ...risks to the subject (or to the embryo or fetus if the subject is or may become pregnant)... If we include women in a decompression study, we had better be sure they ***aren't*** pregnant!

(2)...circumstances under which subject's participation may be terminated...

(3) Any additional costs...

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation... It is certainly prudent to have these items understood in advance.

(5) A statement that ***significant new findings*** developed during the course of the research which may relate to the subject's willingness to continue participation will be provided... Just for example, if the runs are producing 100% spinal cord injury, the subjects deserve to know.

Documentation of informed consent. Informed consent shall ordinarily be documented by the use of a written consent form ***approved by the IRB*** and signed by by the subject...A copy shall be given to the person signing the form.

The role of animal studies.

There is no mention of preliminary animal studies in the OPRR document, but medical school IRB's will probably think about the testing of tables much as they do about the testing of a new drug. In such cases, there is usually a firm background of animal work that supports the scientific merit of a proposal for human study. We should be ready with an explanation if we don't have a background of observations in animals. A good IRB will probably be reasonable about this. If what we want to test is "on the safe side" of a procedure that already has a fair track record, then there would probably be no problem starting with human subjects.

Conceivably, there could be some problems just the same. We might have to admit that there isn't much "clean" experience with some parts of existing procedures. We also know that a schedule that ***ought*** to be ***safer*** just might happen not to be (13), or it might not be ***enough*** safer to be satisfactory. We might be asked to start our experiments farther on the "safe" side than we'd like. We shouldn't be surprised to find an IRB a little skeptical about tables that are "presumed to be adequate without further development."

If there is anything novel about what we propose, or human experience is limited, then we might have a hard time avoiding some work with animals in order to satisfy the IRB. With present knowledge, animal trials should play a role very similar to the function they have in development of a new drug. There, animal trials often send the developers back to the drawing board or the computer.

Here is an example to consider: We would like very much to know whether a "safety stop" - a few minutes at 10 or 20 fsw (3-6 m) - actually can reduce the incidence of CNS-DCS in relatively short, relatively deep "bounce dives." I would certainly want a tentative answer in large animals first, and such a study is on our agenda. Our IRB would probably insist on this before human trials.

Could animal trials be made sensitive enough to be useful in validating procedures striving for a DCS incidence of <1%? I don't know, but it is a challenge we ought to accept. My guess would be affirmative. If we used sheep or goats, the allometric scaling factor would probably be very small.

A more basic question is whether use of animals in validation would be any ***easier*** than working with human subjects. In a rational world, my answer would be a loud "Yes!" First of all, the chance of doing lasting harm to a human subject seems to me very real and very daunting even if remote. Then there are questions of numbers, costs, and the rest...all favoring animals.

But this isn't a rational world. In some countries, it is easier to do studies ***legally*** in human subjects than in animals. The Animal Rights movement and its accomplices are pushing the US in that direction. I can't predict where this will end

or how much hell we will go through on the way.

It is equally difficult to predict what the continuing trend toward litigation is going to do to the practicability of using human volunteers, or whether additional "ethical" hurdles will be set up. If we are wise, we will accomplish as much as we can as soon as we can in both human and animal work.

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DISCUSSION FOLLOWING DR. LANPHIER

DR. YOUNGBLOOD: I would like to point out one dilemma in these experiments which IRB's do not fully cover. We have had an instance in which a subject wanted to withdraw from an experiment when the experiment was actually taking place during a saturation dive. That is something that the experimenters should anticipate because there is no way to get the man out, and he has to understand that situation.

DR. LANPHIER: This should be written in the information that you present to the IRB and the subjects so that they know that there is no way to get out.

CAPT HARVEY: The Navy Medical Research and Development Command has somewhat complicated procedures. I wish ours were as simple as what you presented. We go through a review board which consists of nine people. We have a lawyer, a minister, an outside doctor, plus six people from our own lab, none of whom are associated with the experiment in any way. It is presented to them when it is only a concept. They review it. If they recommend it it goes to Washington, including approval of each form that has to be signed, review of, "Can it be done by non-human experimentation, or some easier way?" "What is the rationale?" All of those things.

Then it goes to the Medical Research and Development Command in Washington, where it goes through another review by another group. When it comes back approved, before each dive the volunteer subjects have to listen to the investigator explain everything to them; it takes about an hour. They then meet with the chairman of the CPHS Committee and he verifies that they have indeed been informed of the thing. They have the right to withdraw at any time during the training period prior to the dives. We have to go through the same procedures again the day before the dives start.

We have fairly good packages put together on our saturation dives. If any of you are getting into this business or you wish to use them as guidelines, I would be glad to send them to you. We are quite open and we have put a lot of thought into them. I do not claim they are perfect. Undoubtedly they can be improved, but we are certainly glad to share them should anyone want them.

DR. LANPHIER: I guess we had better do everything at a university. I have thought of inquiring about the military situation. I am glad to hear that similar requirements, if not much worse, are applied.

CAPT HARVEY: We have got it down to a flow, but it requires a lot of work.

CAPT THALMANN: The military has one advantage; you are not exposing an individual to any more risk than he would normally be exposed to, which makes doing a lot of diving studies a lot easier. Since they are already divers, you do not have to justify the fact that they are diving; the people are already trained to a certain amount.

CHAIRMAN SCHREINER: Thank you. Now, we will have Dr. Weathersby take us into the realm of statistics.

UNCERTAINTY IN DECOMPRESSION SAFETY

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Any validation procedure involves decision in the face of uncertainty. The uncertainty that faces us is just how "safe" a given decompression schedule actually is. A casual observer of the history of human decompression sickness (DCS) will easily accept that when a given decompression procedure is repeated with different people, or even with the same person on different occasions, that the outcome is not constant: DCS may occur or it may not occur.

How can one deal with this inevitable uncertainty? One means is to assert that all cases of DCS are abberations that follow from some special failure of the individual or the circumstances. One then takes on faith (expressed as "professional judgement") that the procedures are safe. Safety of course is never actually defined. For those lacking this faith, an alternative means to deal with uncertainty is to use the discipline invented for describing uncertainty: statistics. Statistics allows us to gather data, combine it, make new predictions - all with some estimate of the uncertainty. Statistics can replace the possible completion of a validation program that concludes "We believe these procedures are safe" with "We estimate that these procedures will yield a DCS incidence under 2% DCS with a 95% confidence in that estimate". The remainder of this paper is concerned with the means to make such assertions. The assumed target incidence of DCS is 1 to 5 %; a higher incidence would be judged as unsafe by many people, and a lower incidence cannot be feasibly tested using analyses to date for reasons that will become apparent.

STATISTICAL METHODS FOR PREDICTING DCS

Single replicated trial

As our first exercise in statistics, consider the following possible test results on a proposed new schedule. In this example, we assume that many subjects have repeated the same dive and decompression. We have repeated all conditions carefully and thus assume that all outcomes are equally valid. Thus our statistical "model" is that there is a single underlying incidence for this decompression schedule. The trial's purpose is to estimate the unknown % incidence of DCS.

Table 1
Uncertainty in Single Repeated Trial

DCS cases	Trials	% DCS	Confidence Limits, % DCS
0	5	0.0	0.0 - 52.2
0	10	0.0	0.0 - 30.9
0	20	0.0	0.0 - 16.8
0	50	0.0	0.0 - 7.1
0	180	0.0	0.0 - 2.0
0	400	0.0	0.0 - 0.9
1	50	2.0	0.1 - 10.7
2	100	2.0	0.2 - 7.0
5	250	2.0	0.6 - 4.6
20	1000	2.0	1.2 - 3.1

The column % DCS is the raw incidence observed. Because of the known variability of DCS, we cannot be sure that this raw incidence is precisely the underlying incidence, and in fact it seldom is. The confidence limit entries in Table 1 are taken from tabulated 95% confidence limits on a binomial distribution (1). Interpretation of the confidence limit is: with the trial result as given, we can assert that the actual underlying DCS incidence is within this range and be correct about 95% of the time. If we only need to be 90% or 80% certain, then correspondingly narrower confidence limits are available.

The first set of entries shows the uncertainty expected for trials that do not result in DCS. As the trial size increases, the uncertainty decreases. If the trial was only 5 safe dives, the incidence might be as high as 52% DCS; if it extended to 50 safe dives, we could be confident that the schedule would not produce over 7% incidence in the long run. About 180 dives free of DCS would be required to feel confident that the schedule in question is actually safer than 2% DCS, and nearly 400 repeated safe dives would be needed to convince us that the schedule is safer than 1%. Clearly, tables accepted after only 5 or 10 safe dives do not provide any real assurance of actual safety.

The next set of entries show the results of several trials that actually did result in DCS. In each case the raw results are 2% DCS, but the confidence range again shrinks with the effort of more dives. With a total trial size of 250 dives we would be confident that the actual incidence was under 5%; over 1000 dives would be needed to ascertain that our observed 2% was actually no higher than 3%.

Seldom do we have the resources to conduct 100 or more trials on each procedure we expect to validate. For testing each schedule, the process of sequential design

can generate some efficiency if the trial is set to test that schedule until a given acceptance or rejection rule has been satisfied (2,3). Nevertheless, the same "ballpark" is present: 20-50 dives can reassure us that the procedure is better than 10%; several hundred are required to assert confidently that the schedule is better than 2%.

Closely related procedures

What if we have many schedules to test and only a limited amount of resources? Can the results on one schedule be used to provide information on another schedule which is similar but not identical? The answer is yes, but it requires another statistical model. The model must predict the probability of decompression sickness, p(DCS), as a function of the important features of the dive. For our next example, suppose that we have a record of DCS outcome after no-decompression dives of the same duration to 3 different depths on some gas mixture. If the time, gas mixture, and trial conduct are all kept constant, the remaining variable to use in the probability model is depth. One possible model for the depth effect is equation <1>:

$$p(DCS) = depth \; / \; (\; depth + D50) \qquad <1>$$

This model says that any depth (greater than zero) has a finite probability of DCS that eventually approaches a p(DCS) of 1.0 (i.e. 100% incidence) as the depth gets very great. The rate of approach is governed by the parameter D50. The principle of Maximum Likelihod is used to estimate D50 and its uncertainty. The actual estimation process is presented in some detail in the references (4,5).

Table 2
Analysis of Trial with 3 Depths

Depth	Trials	DCS	%DCS	Binomial C.L.	Model %DCS	Model C.L.
35	20	0	0.0	0.0 - 16.8 %	5.2 %	2.0 - 14.6 %
45	20	1	5.0	0.1 - 24.9 %	6.7 %	2.5 - 17.8 %
55	20	3	15.0	3.2 - 37.9 %	8.3 %	3.1 - 21.1 %

With the data set given above, D50- the depth for a 50 % incidence - is estimated at 628 with an uncertainty (1 standard error) of 329. As we did in Table 1, the 95% binomial confidence limits are presented. Taking each depth as a completely independent problem, the upper confidence limits range from 17 to 38%. Using the model and its uncertainty and performing a propogation of errors calculation (6), the 95% confidence limits based on the model are found. The table shows that the upper confidence limits shrink somewhat to 15-21 %. The uncertainty has decreased because we have used all 60 dives to estimate the incidence at each depth. Note that the model's prediction of p(DCS) for each depth increases slowly, and that the prediction is well within the binomial limit for each depth. The model also provides a tool to extrapolate into untested territory. For example, we predict from this analysis that a dive to a depth of 75 would give an 11 % chance of DCS (95% confidence limits of 5.4% to 34.1%).

Large Complex Trial

Sometimes it is necessary to deal with a large number of decompression procedures that span a significant range in depth, time, or both. Available resources will dictate that each individual schedule will receive a very small average number of actual human trials. Such was the case in the acceptance tests of the presently used U.S. Navy Standard Air Table (7) which has been analyzed in more detail elsewhere (5). A total of 295 individual decompression schedules were calculated, tested, recalculated and finally published after 568 total trials on 88 test schedules.

For the statistical analysis of such a complex set of exposures, a model is needed that deals with both depth and time in a systematic manner. We applied a set of models that were formulated with an integrated "decompression risk" through and following any dive:

$$p(DCS) = 1.0 - \exp \left(- \int r \, dt \right) \qquad <2>$$

In eqn. <2>, the term r is one of several possible definitions of instantaneous risk, of which eqn. <3> was found to be satisfactory:

$$r = a \; (\; PtN2 - Pamb \;) \; / \; Pamb \qquad <3>$$

Risk was thereby defined as proportional to a (calculated) supersaturation: tissue nitrogen pressure, PtN2, minus the current ambient pressure, Pamb. Normalization by Pamb was found useful in analysis of other data (4). PtN2 was calculated by assuming single exponential gas exchange kinetics (1 traditional "tissue") whose time constant was estimated from the data.

All 568 test dives were used as the data, and a maximum likelihood analysis gave $a = 3.1 \pm 1.1 \times 10^{-3}$ and $T1/2 = 236 \pm 69$ min. The results were checked for several other desirable features before the model was accepted as a good basis for prediction. First, the model had a significantly greater ability to fit the data than did a "null model" which asserted that all exposures were equal in risk. Second, though individual schedules were not replicated enough to provide a meaningful comparison between predicted and actual incidence, categories of predicted dive safety were found to be in accord with subsets of the data. For example, in one of the categories 65 of the trials were

predicted to have a p(DCS) of 2-5% and an average prediction of 3.3%. When the results of those dives were examined, there were 3 cases of DCS for a raw incidence of 3/65 or 4.6%. The 95% binomial confidence limits on 3/65 are 1.0 to 12.9% which comfortably includes the predicted range. Finally, several variants of the model presented above were fit to the same data with no significant improvement. (These included attempts to use other "tissues", but the data did not justify any others.)

The technique of propogation of errors (6) was used to obtain confidence limits on individual schedules. One set of results is given in Table 3 for the attempts to obtain a "safe" decompression schedule from a 130 min dive for 50 min (the fine print of the original report indicates the actual chest depth of the subject was 127 feet).

Table 3
Analysis of Trials for 127/50 Air Dive

Stop Times	30	20	10	Tot.	Outcome DCS/Total	Binomial C.L.	Model C.L.
	----- min -----						
	3	21	21	47	1 / 4	0.6 - 80.6 %	4.0 - 9.3 %
	3	21	27	53	1 / 6	0.4 - 64.1 %	4.0 - 9.0 %
	5	19	28	54	0 / 8	0.0 - 36.9 %	4.0 - 9.0 %

Again, the outcome is based on such small numbers of subjects that the raw binomial confidence limits are enormous. The model confidence limits are much smaller, and in fact are of the magnitude expected for replication of each test schedule with about 300 dives. This extra power has been gained by analyzing all of the dives simultaneously. Note that the rather modest changes in decompression stop times for this dive do not change the predicted safety of the decompression very much: all are about 6%. With the insight gained from the model, we would now conclude that the trial stopped on the third attempt with 8 safe dives because of better "luck" from a 6% dive not because the 54 min decompression is inherently much safer than the 2 other schedules tried.

Limitations

The overall approach is not free of problems. Since the results depend so critically on the data used, time is consumed in verifying data and reconciling inconsistencies. We have found it necessary to return to the original logs and notes in most decompression studies since the published reports did not provide complete information on each dive. Choosing a model is not simple, and requires judgement both on its plausibility and its computational properties. Computer programming and execution is time consuming, and the search for a maximum likelihood when several parameters are being estimated frequently presents numerical problems that delay results. With the type of models used here and about 1000 dives, many hours of running time on a mid-size machine (e.g. PDP 11/70) are required for a solution.

The statistical approach also has problems. The desirable mathematical properties of the likelihood function(8) and the propogation of errors(6) formulas have been documented only for problems "better behaved" than the decompression situation - thus we are operating at the fringe of accepted statistical practice. The danger of misapplication grows with smaller data sets - and 500 is not a large number in this context. Especially susceptible to computing and statistical pitfalls are discontinuous models that have some "threshold" aspect. Even the reporting of uncertainty has a danger. All predictions use a statistical calculation that assumes the underlying validity of the model. Potential "Model Error" will bias the predictions in a direction that statistics cannot deal with. This problem is most apparent when one predicts the p(DCS) for dives which are rather different from those used in the original data set. For example, many potential probabilistic models would be satisfactory for estimating p(DCS) for 40 min dives if the data was rich in 30 and 50 min dives. However, predictions of p(DCS) for 2 hour dives would probably be much less reliable than the propogation of errors confidence limits beacuse of the substantial extrapolation with the model.

Despite those real and potential dangers, substantial progress has been made on a statistically based decompression analysis. The first application demonstrated an ability to describe animal dose-response curves as well as human single-step decompression in helium-oxygen saturation diving (4). Next was an analysis of over 2000 air dives performed in American, British and Canadian naval laboratories (5). Data quality and comparability were serious issues in that study. The most successful model from that analysis was in an optimization scheme to produce sets of standard air schedules with both 5% and 1% expected levels of p(DCS) (9), and was also used in straightforward prediction mode to compare relative safety of air decompression by present U.S. Navy, Royal Navy, and Canadian Forces decompression tables (10). Most recently, some 250 air and N2-O2 saturation decompression dives were analyzed, combined with shorter air data, and used to predict optimized saturation decompression schedules (11).

Summary and Recommendations

Any validation process must address the question: how much do we know about the incidence of DCS with the proposed table? The answer "It looks 'safe' in limited

testing" should no longer be satisfactory. Rather we should accept that DCS is a variable event and use the tools of quantifying variability in constructing the answer. As a binomial random event, each single trial or test dive has very limited information, and only by amassing many hundreds of outcomes can we begin to have a reasonable answer. The contribution of probabilistic models and maximum likelihood analysis is that the hundreds of dives do not have to be replications of individual schedules; they can be single trials or even carefully chosen historical data.

A possible framework for a validation program can now be discussed. The steps outlined below presume that table analysis, development, and testing are done in cooperation. Without further study, no quantitative standards are possible.

1. Construct a probabilistic model
2. Evaluate the model with similar well-documented dives
3. Predict the DCS incidence of proposed tables
4. Conduct a limited trial (few hundred dives)
5. Compare predictions and outcome

5a. If they differ, return to step 1.

6. Use all data to estimate final safety

The proposed scheme looks expensive - and it is. As a final thought, however, let us consider the overall question of cost (Fig. 1). The plot is cost against a measure of safety. Specifically we suggest the upper confidence level of the predicted DCS incidence. To increase certainty in the table's safety (decrease the C.L.), more dives, more analysis, and more money is needed. However, as the confidence limit increases, we can expect more treatments for DCS with their attendant direct and indirect costs. The dotted line adds the problem of legal action for occupational injury. The total cost of accepting a set of tables is then the sum of all the costs, which will have a minimum at some point. I suggest that the overall most economical program will invest heavily in development and keep the operating point near the left of the figure.

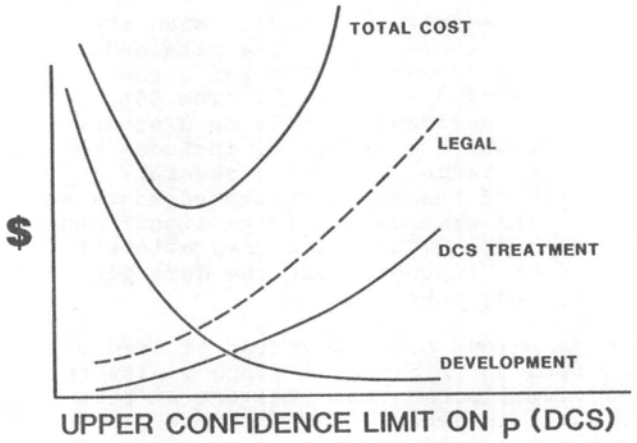

Figure 1. Relationship between cost and confidence limit

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ADDITIONAL COMMENTS BY DR. WEATHERSBY

We have got to accept as a starting point that there is an uncertainty in decompression safety. We have got to accept that decompression sickness is a random event. When we hear of a case of decompression sickness it is not necessarily due to the guy having not gone according to the procedure or having had a drink the night before or any other possible explanations which appear to make this a unique magical event and, therefore, the only exception to this otherwise safe schedule. We have got to accept that individual outcome is unpredictable and that on any given dive there is a chance of each individual getting bent.

We need large numbers in order to have a reasonable degree of confidence in making an assertion about the reliability of a schedule.

Are we dead? Not necessarily. If we can have some systematic way of linking different schedules, we may be able to come out with some degree of confidence, but this will require us to get into the realm of probabilistic models. We have to get out of the view that a decompression schedule could be designed by a model that has a binary outcome: Either you are within the prediction, below the N value, avoid the critical bubble radius, or whatever, or you are not. Rather, we have to convert our models to probabilistic ones that have the form that the probability of getting decompression sickness depends upon the dive, somehow. This is the simplest one I could come up with that would relate to a small set of trials where everything is the same in the small set of trials, except the depth. (Equation 1 in paper.) As this simple model would assert, the probability of decompression sickness depends upon the depth and we have a parameter that needs to be estimated that links the depth with the probability.

You get that from the data by the principle of maximum likelihood. I will spare you the details of how you apply that unless people are particularly interested in it. It is covered in a number of publications that some of you have especially in NMRI Report 85-16.

In a more complicated view, I used for an example the air diving data behind the current set of Navy Standard Air Decompression Schedules. This gets into an important question of data. What we did not do here was to take the published tables as they came out, but rather we went back to the original reports and looked up every one of the actual dives that were done.

The data has to be of sufficiently high quality that it cannot confuse the model. I think this rules out most current operational information because obtaining data of that quality is simply not that high a priority for people who have got to get the job done.

Likewise, if we are going to anticipate trying to use a limited operational trial for validation testing, we have got to consider the quality of the data as being very important.

Regarding data comparability, in principle you can use any data that your model can describe and that you have other reasons for thinking relates to the specific question you want to answer. So, if you want to do air decompression, you can go back in the library or the data bank and look at the results of other air decompressions; but you have got to realize that the data may not be comparable.

For example, the diagnosis of bends from the days "when men were men" at EDU may not be precisely the same definition of bends as we would have from a trial a year ago. You have got to cross that bridge and deal with that. I am not saying how you deal with it in detail, but it is an issue that has to be faced.

Model characteristics can give you a problem, especially models that have threshold aspects to them, like regions that are predicted to be perfectly safe. Any model which has a predicted probability of zero, I think you should stay away from. I wish I could have gotten Dr. Lanphier to include that, because in my estimation a probability of zero should be reserved for theology--we can talk about it as a target, but we should not believe that it has any existence in normal life.

DISCUSSION AFTER DR. WEATHERSBY

DR. BENNETT: Dr. Weathersby knows that through Dick Vann that Duke has adopted that particular method very strongly. We do use all those procedures he has listed there now in the computation of tables. We used them for the saturation decompression tables that we developed

and used in Germany for the GKSS dives. It does give you a very good concept of probability and risk of decompression sickness. I think it is an excellent idea.

CAPT HARVEY: In looking at our proposals for tables for pressurized rescue in the DSRV situation, we are now at the stage of writing the manual and recommending our things by the end of this summer. We are going to include a statistical estimation of what the reliability is at this stage of the game as we put them out. I hope this will set a precedent for others.

THE ROLE OF ULTRASONIC BUBBLE DETECTION IN TABLE VALIDATION

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Introduction

The major problems in the validation of decompression tables are the procedures and criteria required to determine the safety of the tables. Traditionally, the absence of clinical symptoms of decompression sickness (DCS) has been taken to be the ultimate indicator of safety. Acceptance or rejection of a given profile or schedule has depended on an "acceptable" incidence of DCS observed in some set number of dives or on achieving a set number of "clean" dives (i.e., with no DCS). However, there is no standard criterion for rejecting or accepting dive profiles although Homer and Weathersby (1) have recently recommended systematic procedures based on probabilistic considerations. From a statistical point of view, proving the safety of dives using the binary outcome of DCS vs. no DCS with any reasonable degree of confidence would require many more dives than are normally feasible.

The occurrence of DCS is sometimes not well-defined, because diagnosis might rely on a subjective report of invisible symptoms. Mild symptoms could be ambiguous and a diver might not report symptoms if there were a perceived penalty for doing so. Conversely, an anxious diver might report having DCS when the pain had another origin. In reviewing previous work, it is also evident that there are some questions regarding symptoms of DCS and what constitutes a "bend". The criteria used for determining DCS has changed over the years and dive profiles which may have been classified as acceptable in the past may no longer be considered safe.

What is needed is a more objective method for supplementing the traditional DCS approach to assist in making a decision on the safety or risk of dive profiles without having to test a prohibitive number of dives. Ultrasonic monitoring of divers for bubbles can provide such a method. There are two techniques which can be used for monitoring bubbles. The first is the ultrasonic scanning method which enables the detection of gas bubbles in tissues. The second is the Doppler method which enables the detection of moving gas bubbles in the circulatory system. Both methods have their advantages and disadvantages. As ultrasonic methods for monitoring decompression have been reviewed by Powell *et al.* (2), and Brubakk (3), only a brief description of methods will be given here.

Ultrasonic Scanning/Imaging Methods

Ultrasonic scanning methods appear attractive because they enable monitoring of locations where DCS can occur. Combined with acoustic imaging systems, a visual representation of gas bubbles may be obtained. Generally, the equipment required is expensive and bulky, requiring sophisticated electronics and extensive signal processing and computer analysis to differentiate between the background echoes from tissue interfaces and echoes which were not previously present and which may indicate bubble events. There is some problem in quantifying the results. The method is particularly sensitive to movement artifacts and it is desirable to have the subjects restrained, or the portion of the body being studied placed in a support to prevent movement. Ideally, one subject should be monitored continuously. Reproducibility becomes a problem when many subjects must be monitored after a dive. Although a particular spot on the body may be monitored, this could be a disadvantage if bubbles form elsewhere in the body rather than at that spot. Scanning/imaging systems are better suited for laboratory use rather than for routine use in validating tables.

Doppler Methods

The Doppler ultrasonic bubble detector is based on equipment originally developed for the measurement of blood flow. Because bubbles are much stronger reflectors of ultrasound than the particles which are normally in the blood, they can be easily detected over the background signal from the blood. Doppler bubble detectors can be either continuous wave (CW) or pulsed systems.

The CW system is by far the simplest and generally the most useful. It is the one used mainly for bubble detection following decompression. The units designed specifically for decompression applications are relatively low cost instruments and are designed for monitoring the precordial region, either the pulmonary artery or the right ventricle of the heart. Other veins, such as the subclavian or the inferior vena cava can also be monitored with these units. The normal method for detecting bubbles is to listen to the signal from the bubble monitor through headphones and identify and classify the bubbles according to some classification scheme such as the one developed by Kisman and Masurel (4,5) or Spencer (6). It requires extremely skilled and well-trained observers to do a consistent and reliable job. The signal in the precordial region is extremely busy, with contributions from the blood flow, heart valve action, and heart wall motion. Because human judgement is required, the results are subjective and in some cases, the interpretation can vary among observers.

A pulsed Doppler system may provide more flexibility and sensitivity for bubble detection than a CW system because it allows "range-gating" to narrow the sample volume and thus diminish some of the background signals. It may allow better targetting of peripheral veins. The electronics required is more complex and the equipment becomes more expensive. In the experience of DCIEM, there is no significant advantage over CW systems for a well-trained observer.

The Doppler system can be combined with two-dimensional scanning systems as in the echocardiograph to detect bubbles inside the heart. The images can be presented in color to obtain an effective visual representation of the bubbles present in the blood flow. Indications are that the sensitivity is similar to that of conventional Doppler systems (2,3). However, the equipment required is large and very costly thus restricting it essentially for laboratory use.

Automatic Bubble Detection Systems

Because of the human element in the detection and classification of bubbles, there have been several attempts at developing instruments to automatically identify and count bubbles. Most of these rely on the differences in the Doppler signal spectrum between the bubble-free signal and that with bubbles. Some systems used banks of filters or a comb filter to selectively look a specific frequency ranges. Brubakk (3) has described another approach using the difference in the amplitude or intensity between the signal from the flowing blood and that from gas bubbles. The DCIEM approach has been to compute the energy density spectra in a digital computer and compare successive spectra to identify bubble transients. Most automatic bubble detection schemes seem to have some success with animal studies where the Doppler ultrasonic transducers can be implanted around a vein and where the background signal is relatively simple. However, the different methods have not been as successful for the human case with the signal being monitored transcutaneously in the precordial region because the signal is so complex with artifacts that look like bubble transients and have similar frequency spectra.

In the DCIEM approach, some success has been achieved with human data. The conclusion reached was that advanced signal processing involving pattern recognition and artificial intelligence techniques would be required to be able to discriminate between sources of signals which occur on a regular basis (such as valve action and heart wall motion) and signals which result from bubbles. This discrimination and recognition of signals is normally done by the human observer who uses judgement based on past experience and memory of pre-dive reference signals.

Identification and classification of bubbles are still best done by human observers. Although there are some problems with subjectivity, human observers are more accurate overall for human subjects than are automatic bubble detection systems. Automatic bubble detection systems are more costly and at the present time restricted to laboratory use.

Ultrasonic Monitoring for Table Validation

It must be kept in mind that the aim of using ultrasonics for the validation of tables is not necessarily the same or as extensive as for studying the mechanisms or models of decompression and DCS. The main purpose of using ultrasonics is to obtain comparative information to assist in determining whether or not a table is safe or hazardous. If ultrasonic methods are to be used by all involved in validating tables, then all testers should be using a common system. Such a system should be widely available, relatively inexpensive, easy to use, allow monitoring of subjects quickly, be relatively accurate, valid and reliable. It is important that procedures be standardized for carrying out the dives, monitoring divers, analysing data, and reporting of results to provide a common basis for decompression table validation.

Of the ultrasonic methods described briefly above, the Doppler method is the most useful for routine monitoring and providing the most useful, on-the-spot information to assist in evaluating the decompression stress of a dive profile. (It should be noted that the Doppler system is useful only for post-dive analysis and not for controlling or managing decompression. The only exception is during decompression from saturation when the Doppler information can be used to control the decompression profile). The scanning/imaging systems are generally too large and expensive for routine use and impractical for a large number of subjects at one time. Such systems are more suited for laboratory use. On the other hand, the Doppler system, in particular, the CW system, is battery-operated, portable, compact, inexpensive, rugged, and easier to use for routine monitoring of a large number of subjects after a dive.

In recent years, the Doppler ultrasonic bubble detector has become more widely used as a means to evaluate the safety of decompression procedures and validate tables. DCIEM has been using this technique extensively since 1979. In particular, the development, validation and acceptance of the new DCIEM/Canadian Forces Air Decompression Tables was based on the results from Doppler monitoring. These results were used to supplement the information obtained using the traditional method of DCS vs. no DCS. Currently, DCIEM is developing a new set of helium tables using Doppler monitoring as a critical element in the validation process. DCIEM uses the Sodelec DUG and the TSI Doppler Ultrasonic Bubble Detector (this latter unit has been designed specifically for DCIEM). Sources for commercially available Doppler bubble detectors are given in Appendix 1. The bubble classification method used is the KM method which was developed jointly by DCIEM and the Centre d'Etudes et de Recherches Techniques Sous-Marines, France.

Other laboratories or organizations which have been using the Doppler bubble detector for manned dive testing include CERTSM, US Navy Experimental Diving Unit, US Naval Medical Research Institute, US Naval Submarine Medical Research Laboratory, the Admiralty Research Establishment (PL) in the U.K., NUTEC in Norway, DFVLR (Germany), IAPM (Seattle), and Duke University. Many of these organizations are now using the KM method for classifying bubbles.

Standardized Doppler Monitoring Procedures

The following recommendations for Doppler monitoring are based on DCIEM's procedures.

Frequency of monitoring. The objective is to obtain a history of bubble production for each subject in the dive. It is not generally possible to monitor the divers continuously, thus the divers must be monitored periodically. For most non-saturation dives, monitoring should begin soon after the divers reach the surface, and should be repeated at half-hour intervals for at least two hours. Delays of an hour or more have been observed before bubbles were detected, and elevated bubble counts have been observed, in some cases, for periods longer than six hours following severe dives less than an hour in duration.

Monitoring sites on the body. Only moving intravascular bubbles can be found with the Doppler method. The primary site to be monitored should be the right ventricle (the precordial site) since an estimate of the rate of bubble production for the entire venous system can be obtained, assuming that the bubbles persist long enough to reach the heart. To supplement observations from the precordial site, the subclavian veins (both left and right shoulders) can be monitored. Bubble signals at these sites are unambiguous; however, they should

not be used as an alternative to the precordial site because they do not cover the whole body.

Subject position. The subject should be standing or lying down for the evaluation. Either position produces good results, so the choice can be dictated by convenience. The evaluations should be done for two conditions – one with the subject at rest, and another after the subject has moved in some defined way. For example, for the precordial evaluation, a standing subject would do a deep knee-bend – squatting down and standing up, in a smooth, continuous motion. For the subclavian site, the subject would clench his fist. The movement case is useful because it often produces a shower of bubbles that are easily identifiable.

Doppler hardware and training. The instrument used should be a simple continuous-wave (CW) Doppler ultrasonic device operating at 5 MHz developed specifically for detecting bubbles (see Appendix 1). CW Doppler instruments developed for clinical use tend to lack sensitivity and durability. Monitoring is done by trained observers listening to the signals through headphones. Training of the observers should be according to the Kisman-Masurel (KM) method (5) or the Spencer method (6). Both methods give similar results but it is believed that the KM method is easier to learn and use.

Signal classification. The bubble signals are converted into "bubble grades" using the KM or Spencer signal classification method. In the KM method (Appendix 2), a 3-digit code represents the approximate number of bubbles heard in each cardiac cycle, the percentage of cardiac cycles with that approximate number of bubbles, and the amplitude of the signal relative to the background cardiac sounds. This 3-digit code is converted into a global bubble grade categorized by 0, I, II, III, and IV. The grades can be further divided with + and - to get better resolution. In the Spencer method (Appendix 3), the number of cardiac cycles with bubbles is only considered. Bubble grades are from 0 to IV. It is recommended that bubble grades be represented as Roman numerals rather than Arabic numerals to emphasize that these grades represent **classifications** and **not** numbers.

Recording of data and presentation of results. Accurate record keeping is a necessity. For each monitoring session of the subject, three assessments of the 3-digit KM code should be obtained and recorded for each site and condition (i.e., precordial, rest and movement; left subclavian, rest and movement; right subclavian, rest and movement) with the time of observation relative to the start of decompression or, alternatively, when the surface was reached. The KM code can then be converted to bubble grades. In addition to recording the information on paper in a standard format, the audio signal from the Doppler bubble detector for each assessment should be recorded on magnetic tape for future reference and review. Each record should be clearly identified with the name of the subject, the monitoring location and condition, and the time of observation.

Reporting and analysis of the bubble information is an area that still requires some definition. The most convenient method is to present the peak bubble grades for all subjects in a particular dive in tabular form or graphically in a histogram. This allows a ready comparison between different dive profiles and can show the relative decompression stress of the profile. Statistical analysis of the data must be done with some care. Doppler data belong to a class of data called categorical data. Parametric tests such as t-tests or arithmetic operations such as means and variances should not be applied to bubble grades (7). Appropriate statistical techniques involving non-parametric statistical tests exist and should be used.

Bubbles as Indicators of Decompression Stress

If the association between bubbles and DCS could be established, the criterion for accepting or rejecting profiles could be expressed as a function of the bubbles observed. Doppler-detected bubbles are not normally believed to be the cause of DCS, but their presence in the circulation may be indicative of bubbles elsewhere in the body. Large numbers of bubbles are not necessarily accompanied by DCS, nor do they directly lead to observable symptoms of DCS. However, the risk of DCS does appear to be increased as incidents of DCS are generally accompanied by bubbles. Furthermore, there is some evidence that intravascular bubbles may cause subclinical damage that may have long-term effects; thus dives which produce many bubbles should be avoided (8).

There have been several surveys of Doppler data which have shown a relationship between intravascular bubbles and DCS. Table 1 shows the percentage of DCS events vs. bubble grades from DCIEM dives and from other sources (9,10). The DCIEM results include a mix of dives all done on air, including no-decompression dives, decompression on air only, with oxygen decompression, and surface decompression with oxygen. (Grade IV bubbles at rest are relatively rare and the results shown are for only 2 subjects (1 DCS)). The US Navy results include both bounce and saturation dives on nitrogen-oxygen and helium-oxygen and the Duke University dives are bounce dives on nitrogen-oxygen and helium-oxygen. The "Other" dives, from a variety of sources, are all air except for 17% on helium. These dives include some DCIEM air dives as well.

Table 1. Percentage of DCS vs. Precordial Bubble Grades

Source		N	Bubble Grades				
			0	I	II	III	IV
DCIEM	Rest	1539	0.8	0.8	5.5	14.0	50
	Move		0.5	3.3	5.0	7.9	13.9
USNavy(9)	Rest	472	2.5	2.6	5.3	10.5	0
	Move		3.0	0	2.6	2.9	42.9
Duke(10)	Move	540	1	1	0	19	41
Other(10)	Rest	834	0	6	10	31	35
	Move	850	0	1	1	13	33

Table 1 shows that, in general, the incidence of DCS is higher for the higher bubble grades and that the incidence of DCS is low when few or no bubbles are detected. Thus, for the purposes of table validation, we can say that dives which produce many bubbles in a majority of the divers can be considered to be stressful with a higher risk of DCS and should be avoided. Conversely, dives which produce few or no bubbles in the majority of the divers can be considered safe. To establish some simple criterion for estimating the acceptability of a table, DCIEM has selected, as a limit, dives which produce bubbles of Grade II or greater in 50% or more of the subjects as being stressful. This figure is arbitrary and may possibily have to be changed as more data are acquired for table validation by different organizations.

Factors that complicate dive table validation with the Doppler bubble detector are that individual divers can be variable and respond differently to the same dive profile at different times. There may be considerable differences in the response among different subjects. Thus it is necessary to use some judgement in interpreting the results.

There are two main advantages to using Doppler monitoring. Doppler monitoring provides more data than observing the incidence of DCS. For example, in the 1539 DCIEM dives, bubbles were observed in 34%, whereas only 2.6% resulted in DCS. Thus not as many dives are required to establish a safe table as are required if DCS is the only criterion. It is often possible to use bubble observations to compare the results of two dives, even in the absence of DCS. If no bubble results were available, it would have to be concluded that there were no observed differences. However, one profile may generate many bubbles in most of the subjects whereas the other may generate only a few bubbles in the subjects; thus a difference between the two profiles becomes evident. In addition, in the absence of DCS and bubble results, there may be no way to determine how close to the DCS threshold these dives are. It is unlikely that an experimental dive program, for example, to determine a DCS threshold, would be approved today if a high incidence of DCS were considered likely. As decompression procedures become safer, decompression testing could involve profiles that produce few or no cases of DCS, hence making the bubble results more important. It should be noted that one need not "bend" divers to know whether or not a dive is safe.

Bubble results are more objective than DCS results. Although there is some subjectivity in classifying bubbles, well-trained observers will generally be able to identify the presence of bubbles. Success in detecting bubbles depends on the vigilance of these highly trained observers, and although bubbles can sometimes be hard to detect, the results cannot be hidden by the diver. As indicated earlier, divers may sometimes not report symptoms of DCS or conversely, report symptoms, because of apprehension and uncertainty, which may not be directly attributable to the decompression.

The main disadvantage of Doppler ultrasonic bubble detection is that it is time-consuming and labour-intensive. For a typical bounce-dive, the divers should be monitored periodically for several hours following the dive. The work becomes tedious, but demands concentration.

Summary

Ultrasonic bubble detection can have an important role in the process of decompression table validation. The Doppler ultrasonic bubble detector, at the present time, is the most useful and can give comparative information as to the decompression stress of the dive even in the absence of DCS. Thus ultrasonic bubble detection can give far more information than the traditional DCS vs. no DCS approach with fewer number of dives. It is not necessary to bend divers to determine if dives are unsafe. However, it is important that all table testers standardize on procedures and methods so that there is a common basis for comparing results.

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Appendix 1

Suppliers of Doppler Ultrasonic Bubble Detectors

a) Techno Scientific Inc., 60 Caster Avenue
Woodbridge, Ontario, Canada L4L 4X2
b) Sodelec, 31, Traverse Prat,
Pointe-Rouge, 13008 Marseille, France
c) Institute of Applied Physiology and Medicine
701 - 16th Avenue, Seattle, Washington, USA 98122

Appendix 2

The KM Code for Classifying Bubbles

Three parameters are used to describe the bubble signal (Ref. 4,5). Each parameter is assigned a classification from 0 to 4. The first, frequency, represents the number of bubbles per cardiac period (Table A1).

Table A1. Frequency parameter

Code	Frequency (f)
0	0
1	1 - 2
2	several 3 - 8
3	rolling drumbeat 9 - 40
4	continuous sound

For code 4, the bubbles are so numerous that they cannot be individually distinguished.

The second parameter differs for the two monitoring conditions - rest and movement (Table A2). For the rest condition, it represents the percentage of cardiac periods having a specified bubble frequency. For the movement condition, it represents the number of successive cardiac periods having at least a specified bubble frequency (i.e., the first parameter) following the movement. The first such period must occur within 10 heart beats following the movement.

Table A2. Percentage/duration parameter

Code	Rest Percentage (p)	Movement Duration (d)
0	0	0
1	1 - 10	1 - 2
2	10 - 50	3 - 5
3	50 - 99	6 -10
4	100	> 10

The third parameter is the amplitude of the bubble signal, which is compared to the amplitude of the normal cardiac sounds (Table A3).

Table A3. Amplitude parameter

Grade	Amplitude (a)
0	no bubbles discernible
1	barely perceptible, $A_b << A_c$
2	moderate amplitude, $A_b < A_c$
3	loud, $A_b \simeq A_c$
4	maximal, $A_b > A_c$

The three parameters are combined in the form 'fpa' for the rest case and 'fda' for the movement case to give the KM code for each assessment. This KM code is reduced to a single Bubble Grade (g) according to Table A4.

Table A4. KM Code → Bubble Grade

fpa fda	g	fpa fda	g	fpa fda	g	fpa fda	g
111	I–	211	I–	311	I	411	II–
112	I	212	I	312	II–	412	II
113	I	213	I+	313	II	413	II+
114	I+	214	II–	314	II	414	III–
121	I+	221	II–	321	II	421	III–
122	II	222	II	322	II+	422	III
123	II	223	II+	323	III–	423	III
124	II	224	II+	324	III	424	III+
131	II	231	II	331	III–	431	III
132	II	232	III–	332	III	432	III+
133	III–	233	III	333	III	433	IV–
134	III–	234	III	334	III+	434	IV
141	II	241	III–	341	III	441	III+
142	III–	242	III	342	III+	442	IV
143	III	243	III	343	III+	443	IV
144	III	244	III+	344	IV–	444	IV

Appendix 3
The Spencer Scale for Classifying Bubbles

The Spencer scale is used for precordial signals with the subject breathing quietly and otherwise motionless in a sitting or supine position (Ref. 2,6).

Grade 0 A complete lack of bubble signals.

Grade 1 An occasional bubble signal discernible with the cardiac motion signal with the great majority of cardiac periods free of bubbles.

Grade 2 Many, but less than half, of the cardiac periods contain bubble signals, singly or in groups.

Grade 3 All of the cardiac periods contain showers of single-bubble signals, but not dominating or overriding the cardiac motion signals.

Grade 4 The maximum detectable bubble signal sounding continuously throughout systole and diastole of every cardiac period, and overriding the amplitude of the normal cardiac signals.

DISCUSSION FOLLOWING MR. NISHI

CAPT HARVEY: NSMRL has had the pleasure of working with DCIEM for some time. We have been using dopplers for 17 years that I know of at NSMRL. There is an art to using a doppler. There is an art to getting the signal correctly and there is an art to interpreting it. We have tried double blinds; we tried lots of approaches. Currently, we are interpreting it ourselves, then we have it reinterpreted at DCIEM to try to get some kind of consistency. My question is: How much of the poor correlation between doppler results and decompression sickness results do you think is due to errors in the art of "dopplering?"

MR. NISHI: There is probably quite a bit. Even among our observers, we have some differences. If there is some difficulty in a particular individual who is being monitored, the observer may ask someone else to check the original. Brian Eatock who used to head up the doppler team sometimes got his group together after a dive series and they would review some of the recorded signals. They would all listen to the same signals and each one would give his evaluation of the signal. We tried to keep everyone talking on the same terms.

CAPT HARVEY: As a follow-on to that question, do you think that computer analysis, if you will, artificial intelligence to interpret, will offer us much improvement.

MR. NISHI: It could help, but somebody is going to have to come up with a lot of money to develop this system. We have spent over $200,000 on our system and we are going to give it up since it is not really worthwhile to continue.

DR. LAMBERTSEN: If you picture that the appearance of bubbles is an undesirable consequence of decompression, and now the non-appearance of bubbles is causing trouble elsewhere, how can you relate constructively the doppler measurement to any but the more rapidly evolving components of gas, as opposed to the less rapidly evolving components that do cause the pain and the spinal injury? It should be recognized that the bubbles that you are seeing are part of the problems and the bubbles that you are not seeing are part of the problem. To try to correlate the bubbles you are hearing with those that are hurting may not be possible.

MR. NISHI: There are difficulties. It is not a perfect tool, but it is a good tool to give you supplemental information.

Just another comment on the high bubble grades. Masurel recommends that people be treated with surface oxygen for Grade III bubbles at rest and be recompressed for Grade IV.

DEVELOPMENT AND VALIDATION OF DEEP BOUNCE AND OTHER DECOMPRESSION PROCEDURES IN THE LABORATORY

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Deep Bounce Dive Development and Validation

It is not proposed to repeat here the full details concerning our 1974-75 work on the "Theory and Development of Sub-Saturation Decompression Procedures for Depths in Excess of 400 Feet" which is available elsewhere (1). Nevertheless in order to understand the philosophy of validation of deep decompression tables in the laboratory in the early 1970's compared to current problems, it is necessary to review briefly what was done.

During the 1970's commercial diving companies were extending their diving depths to 400 and 500 ft and needed short 30 min or so bottom times. Companies competed for business quite often on the basis of the time for such dives. The less the time, the lower the cost and the greater likelihood of obtaining a contract. However, if decompression sickness (DCS) developed, then it would increase the time and costs. Companies therefore developed their own tables and were highly secretive about their development, degree of testing, or DCS incidence in use.

The incidence of DCS for field use of such tables was believed to be some 10-30% and there was also considerable oxygen toxicity in the form of numbness of fingers and toes, shortness of breath, etc. New regulations in the North Sea and Norwegian operations offshore required evidence of the safety of decompression tables prior to use which increased the need to validate such tables.

Thus at Duke's F.G. Hall Laboratory an unusual combination of private, university, government and commercial research funds were brought together to develop and test decompression tables to 500 ft. This would be done in the sophisticated chambers of a major medical center, utilizing the Institutional Review Board (IRB) procedures for human experimentation developed by NIH for use by active, research involved, medical centers.

The financial support for the work to be done was provided by the Harbor Branch Foundation and Oceaneering International Inc. who also provided proprietary information on tables, and company employed commercial divers. International Underwater Contractors also provided support.

Procedures for such work, then as now, is first to submit to the Duke IRB a statement of the research to be done, by whom, with what subjects, and where. Over the years the requirements of the IRB have become stronger. Thus any use of government funds for human research requires automatic review by the IRB. This determines that the rights and welfare of the subjects involved are adequately protected and the risks to an individual are outweighed by the potential benefits to be gained by the knowledge obtained, and also that informed consent is to be obtained by methods that are adequate and appropriate. In addition, a basis for annual continuing review is required with an annual report of progress and any problems that occurred. Full details of the procedures are given in "The Institutional Guide to DHEW Policy on Protection of Human Subjects" (2); "Protection of the Individual as a Research Subject" (3) and "Protection of Human Subjects" (4).

The basic elements of informed consent are:

1. A fair explanation of the procedure to be followed including an identification of those which are experimental.
2. A description of the attendant discomforts and risks.
3. A description of the benefits to be expected.
4. A disclosure of appropriate alternative procedures that would be advantageous for the subject.
5. An offer to answer any inquiries concerning the procedures.
6. An instruction that the subject is free to withdraw his consent and to discontinue participation in the project or activity at any time.

In addition, the agreement should include no exculpatory language through which the subject is made to waive or appear to waive any of his legal rights or release the institution or its agents from liability for negligence. Consent forms are signed and witnessed.

Therefore a full report of what was intended to be done was submitted to the IRB explaining we would be utilizing fully trained commercial divers who would likely be already diving to such depths in the ocean plus an appropriate consent form outlining the risks of pressurization including decompression sickness, sinus or ear problems, aseptic bone necrosis and equipment failure.

Certain requirements also were requested for the finished tables by the companies concerned. These included:

(a) Avoidance of CNS decompression sickness
(b) No DCS deeper than 60 ft
(c) No vestibular DCS
(d) Optimal use of O_2 without toxicity
(e) Minimal use of BIBS (Built In Breathing System)
(f) Simple table design for easy comprehension
(g) Minimal number of gases
(h) Use of stages rather than linear ascent.

An arbitrary test standard of 12 no DCS dives was agreed. Bottom gas was standardized at 93% He/7% O_2. Two dives per week were planned by 3 or 4 subjects with one subject working with his arms (VO_2 0.6 - 2.33 l/min) while wearing standard commercial diving equipment in cold water. Compression rate was set at 100 ft/min with a bottom time of 30 min. Precordial doppler was used to determine the presence of bubbles during the decompression.

No theoretical concept of table development was proposed initially. Instead the research started by evaluation of an 'in use' Oceaneering table called "the parent". This table had been calculated using Haldanian concepts with a ratio and tissue half-time matrix acquired through empirical operational experience. The table had two problems, vestibular DCS at the air change at 160 ft, and DCS Type I at 30 to 50 ft. The table was 636 min long and used a lot of oxygen for a Unit Pulmonary Toxic Dose of 838.

Development and validation of the table now became an empirical serial event (Table 1). Thus the air shift was dropped to 130 ft and the deeper stops were extended. Tables A-D were compiled and tested. A and B with 20 mins bottom time had no DCS in 12 dives with a UPTD of 755. However at 30 mins the C, D versions produced DCS in 2 'wet' divers at 100 and 110 ft and a further incident at 15 ft.

At this time a theoretical Haldane matrix was applied using 16 tissue half times between 5-600 mins and the ratios of N_2 + He/ambient calculated at each 10 ft depth increment. From this the limiting ratio (the highest) was recorded for each depth.

Table development then consisted of reducing the ratios appropriately and the new table tested. In this series of tables the precordial doppler proved useful as bubble sounds were well correlated with the likelihood of DCS.

However in the ensuing tables DCS occurred consistently at 20-50 ft in the cold, wet working diver. By table J the ratios from 500 to 200 ft were reduced significantly to 1.06 to 1.08 from 1.13 to 1.14. After 9 safe man dives, vestibular DCS occurred at the 140 to 130 ft air change. This was therefore dropped to 100 ft. By now the UPTD was too high at 922 and post dive DCS was occurring.

It was decided then that Haldane concepts did not seem practical and to examine diffusion and nil-supersaturation methods instead. Without a lot of detail here, these tables, which involved a 5 ft/min air ascent to the surface from 25 ft, later modified with pure oxygen from 30 ft, continued with monotonous regularity to produce DCS limb pains not selective for the wet working diver (Table 2).

Finally a Haldane model was used for the first part of decompression to 190 ft and then the diffusion model to the surface. This produced Table 500 X which had a UPTD of 780 and a total time of 757 mins. It produced no DCS in 22 man dives. This included two dives from a lock-out submersible at sea.

Interestingly in the nil-supersaturation tables, where diffusion constants were utilized, the DCS was random between working and non-working divers and no doppler bubbles were heard. With the perfusion limited Haldanian method, bubbles were heard and the DCS was predominantly in the wet working diver.

Over a period of 15 months, 113 dives were made during 1974-75 to 500 ft and 600 ft with 374 man exposures. There were 55 cases of DCS for an incidence of 14.6%. Treatments used mostly U.S.

Table 1. Haldane-type tables

	Depth	Parent	A	C/D	E	F	Depth	G	H	I	J	L	N	
He/O_2	500	1.28	1.27	1.27	1.27	1.27	500	1.34	1.34	1.27	1.09	1.01	1.01	1.01
	450											1.26	1.26	1.26
	400										1.18			
	350	1.43	1.32	1.32	1.32	1.32	330	1.25	1.22	1.32		1.15	1.15	1.15
	300										1.16	1.13	1.13	1.13
	290										1.15	1.10	1.10	1.10
	280	1.28	1.14	1.14	1.14	1.14	305	1.22	1.21	1.14	1.12	1.08	1.08	1.08
	270		1.14	1.14	1.14	1.14				1.14	1.10	1.06	1.06	1.06
	260		1.13	1.13	1.13	1.13				1.14	1.08	1.06	1.06	1.06
	250	1.20	1.13	1.13	1.13	1.13	255	1.16	1.15	1.13	1.06	1.06	1.06	1.06
	240	1.20	1.13	1.13	1.13	1.13				1.13	1.06	1.06	1.06	1.06
	230	1.18	1.13	1.13	1.13	1.13	235	1.16	1.16	1.13	1.07	1.07	1.07	1.07
	220	1.18	1.14	1.14	1.14	1.14				1.13	1.07	1.07	1.07	1.07
	210	1.18	1.14	1.14	1.14	1.14	215	1.17	1.17	1.14	1.07	1.07	1.07	1.07
	200	1.19	1.15	1.15	1.15	1.15	200	1.16	1.16	1.14	1.07	1.07	1.07	1.07
	190	1.20	1.15	1.15	1.15	1.15	190	1.15	1.15	1.15	1.07	1.07	1.07	1.07
	180	1.19	1.14	1.14	1.10	1.05	180	1.15	1.15	1.15	1.07	1.06	1.06	1.08
	170	1.15	1.11	1.11	1.06	0.99	170	1.10	1.12	1.12	1.08	1.06	1.06	1.07
	160 Vest*	1.13	1.11	1.11	1.02	0.96	160	1.11	1.11	1.10	1.08	1.06	1.06	1.07
Air	150 Vest**	1.10	1.10	1.10	1.01	0.95	150	1.11	1.11	1.10	1.08	1.07	1.07	1.09
	140	1.09	1.09	1.09	1.00	0.95	140	1.09	1.09	1.09	1.08 Vest*	1.07	1.07	1.09
	130	1.09	1.09	1.09	1.02	0.97	130	1.07	1.12	1.10	1.07	1.07	1.07	1.08
	120	1.10	1.11	1.10	1.05	0.99	120	1.07	1.12	1.09	1.07	1.08	1.08	1.09
	110	1.12	1.13	1.12	1.09	1.02	110	1.09	1.12	1.08	1.06	1.08	1.08	1.08
	100	1.08	1.08	1.14**	1.11	1.05	100	1.09	1.11	1.09	1.05	1.08	1.08	1.08
	90	1.07	1.07	1.16	1.15	1.09	90	1.11	1.11	1.08	1.05	1.08	1.08	1.08
	80	1.11	1.11	1.18	1.18	1.14	80	1.13	1.12	1.09	1.06	1.08	1.08	1.09
	70	1.10	1.10	1.19	1.20	1.18	70	1.16	1.15	1.09	1.09	1.08	1.08	1.08
	60	1.12	1.13	1.24	1.25	1.18	60	1.11	1.10	1.10	0.99	0.98*O_2	1.09	1.09*
O_2/Air	50*	1.04	1.05	1.13	1.15*	1.12	50	1.14	1.03	1.02*	1.04	1.00	1.06	1.06*O_2
	40	0.97	1.00	1.06	1.09	1.03	40	1.03*	1.02*	1.01	1.04	0.98	1.09	1.09
	30**	1.03	1.03	1.09	1.13	1.14	30	1.06	1.07	1.08	1.03	1.15	1.26	1.22
	20	1.14	1.10	1.15	1.19	1.29*	20	1.24	1.25	1.26	1.19	1.20	1.31	1.59
	16										1.30	1.31	1.45	
	15		1.38	1.27*	1.33		15							
	10	1.48		1.48		1.63	10	1.60	1.61					
	8										1.57	1.58	1.74	
	5						5							
	S	1.46	1.56	1.62*	1.96	1.66	S	1.60	1.61	1.63	1.75	1.76	1.74	1.76
Total Time		636	575	585	624	749		629	570	617	742	796 (4 hr post*)	971	849
O_2, UPTD		838	755	697	721	986		O_2 783	O_2 788	819	842	922	847	886
Problems			-	4	1	1		1	1	1	1	1	-	2
No Exposure			12	20	12	6		3	3	6	9	12	3	21

Table 2. Diffusion/Nil Supersaturation Tables

Schedule	Depth, First Stop	Last Stop To Surface	Surfacing Ratio	He Constants	N_2 Constants	Total Time	O_2, UPTD	Bends Incidence
POPPA 1	220	25 Air	2.41	42/190	34/190	915	721	All 3 divers, no bends, no bubbles
POPPA 2	220	30 Air	2.49	42/190	34/280	880	714	TC, knee pain 4 hr post-dive DM, mild shoulder 1 1/2 hr post dive
QUEBEC	250	30 Air	2.76	42/190	32/330	826	735	DF, both knees 5 hr post-dive CM, onset depth 7 ft, right knee PK, bubbles (wet)
ROMEO	250	25 Air	2.22	39/230	32/330	1017	823	6 clear
SUGAR	250	25 Air	2.38	40/210	32/330	976	772	3 clear
TANGO	250	25 Air	2.49	41/190	32/330	865	710	DF, slight bubbles on surface DF, knee pain 8 hr post-dive, 2 clear SN, knee pain 8 hr post-dive, 2 clear (wet)
UTAH	220	25 Air and O_2	2.34	41/190	32/330	863	713	JB, 2-3 ft, left knee (wet), 8 clear
VICTOR	220	25 Air and O_2	2.36	41/210	32/330	833	713	CM, 10 ft, both elbows (wet), 5 clear
VICTOR (2)	210	25 Air and O_2	2.43	41/210	32/330	856	742	JM, both knees at 6 ft (wet), 10 clear
VICTOR (3)	210	25 Air and O_2	2.30	41/210	32/330	875	787	JM, 1 hr post-dive, left knee, 5 clear
WHISKEY	210	15 Air and O_2*	2.22	41/210	32/330	688	712	JB, 42 min, right knee, 1 clear DM, 3 1/2 hr, both knees (wet)
X-RAY	310	10 Air and O_2*	2.22	41/210	32/330	757	780	20 clear

*Alternating air and oxygen.

Navy Table V but for cases deeper than 30 ft a procedure developed at Duke was utilized which was completely successful.

The table X-Ray was eventually utilized offshore commercially in very arduous, very cold (55-60°F) work condition with divers wearing unisuits. They could only stay down 20 mins due to being so cold, and simple limb pain DCS occurred at 100 ft. This also occurred in better conditions and the table was known for its risk of DCS at 100 ft and was dropped after 6 months.

In fact on the basis of this and other failed attempts to generate DCS free tables to 500 ft or 600 ft commercial companies later switched to saturation decompression procedures for depths deeper than 350 ft and those depths still are regarded as most difficult for 'bounce' diving decompression.

In the light of this work does table validation in the Laboratory make sense? It is pertinent that the Royal Navy tested deep oxygen-helium tables in the 1960's first in the dry chamber, then in a large 'wet' simulator and finally at sea off the dive support vessel HMS Reclaim. No problems were experienced until the final sea trials in the Mediterranean when DCS was experienced on virtually every dive! The trials were stopped and the tables brought back for further testing when again DCS started to appear! The most likely reason for this was ignoring the effects of cold. There are many other experimental factors to be considered in laboratory validation of decompression tables if it is to be of practical value. These are considered below.

Acceptable Decompression Risk

Experience indicates that decompression sickness (DCS) is a statistical phenomenon and that a finite DCS risk exists for many dives of useful depth and bottom time. A practical dive profile should have a low risk but not so low that reasonable work cannot be accomplished. It is desirable that serious symptoms should be completely avoided, but this may not be possible. It is less clear what risk is acceptable for minor symptoms which could vary between 0.1 and 2% depending upon the availability of recompression facilities.

The notion of an acceptable decompression risk applies to the full depth and bottom time of a dive and should be distinguished from the more familiar diving statistics such as those reported by Berghage and Durman (5) in which 16,170 Navy dives between the years of 1971 and 1978 had a DCS incidence of 1.25%. As most of these were working or training dives, the actual depths and bottom times were frequently less than those permitted by the schedules that were used.

The unpredictable nature of decompression sickness is, in large part, due to our inability to measure some of the key risk factors and to appreciate their influence. Depth, time, and gas mix can be measured accurately and are well known to affect risk, but other factors such as exercise, adaptation, immersion, and thermal state are difficult to measure in the laboratory, let alone in the field, and are frequently ignored during decompression tests. There is both physiological basis and empirical evidence that the conditions under which decompression trials are conducted are important determinants of risk. If these conditions are not well defined and tightly controlled and if the decompression procedures are used in the field under other conditions, a different risk will apply (6,7).

The solution to this problem might appear to be to opt for maximum safety and to test under the worst conceivable conditions which would rarely be encountered. Unfortunately, this might increase the decompression time by a factor of 3 or more in situations where much shorter decompressions would suffice. This problem is illustrated in Fig. 1 which shows decompression times for a series of MK 15 dives to 100 fsw for 60 min (7).

The x-axis defines the conditions under which the schedules were tested, and the y-axis shows the total decompression time. Each schedule is represented by a bar graph whose height is proportional to the decompression time. The figures at the top of each bar are the number of DCS incidents over the number of trials. An unfilled bar indicates a schedule for which DCS did not occur. Dry, resting exposures required only 40 min of decompression. In wet trials, where the divers exercised at depth and rested during decompression, both the DCS incidence and decompression time increased. With light exercise at an oxygen consumption of 1 lpm, 90 min of decompression were required. With moderate exercise at 2 lpm, 115 min were needed, but this was insufficient to prevent DCS during heavy exercise at an oxygen consumption of 2.8 lpm.

Because of the uncertainties concerning DCS incidence and acceptable risk, decompression accidents should be expected and must be prepared for in planning a dive. Communications should be available for notifying an accident response system (such as the Divers Alert Network in the United States (8)), adequate ground or water transportation should be pre-arranged, oxygen should be on hand for surface use, and recompression facilities should be available within a reasonable distance. Perhaps more important, divers should be educated during their initial training that there are no magic depth time limits which confer immunity from decompression sickness or from diving accidents in general.

How Many Trials per Schedule?

Related to the problem of acceptable risk is the question of how many times a dive profile should be tested before being accepted as safe. Berghage found that the binomial distribution provided a satisfactory description of the DCS variability in mice and suggested it might also apply to humans (9). The binomial distribution may be used to relate the DCS risk to the confidence interval of achieving this risk in a specified number of tests. Suppose we wanted to be 95% confident that the DCS risk for a given dive was not greater than 5%. This confidence interval could be achieved by 60 tests without incident, 90 tests with one incident, or 115 tests with 2 incidents. Homer and Weathersby pointed out that the number of required trials could be reduced to some extent by sequential analysis which makes use of the order in a sequence of dives at which an incident occurs (10). By sequential analysis, there is a higher probability that a profile is unsafe if DCS occurs in the first trial instead of in the 40th trial.

It would be desirable to test to these conventional levels of statistical reliability or to even higher levels, but the cost and manpower requirements of the vast number of trials makes this virtually impossible. Previous testing programs reflect this difficulty. Haldane, for example, tested his schedules twice (11). The U.S. Navy Standard Air Schedules were tested 4 times (12). During the 1970's, commercial schedules were tested 12 times (13). More recent programs have used 20 to 40 tests (7,14). When so few tests are conducted, it is essential to achieve the greatest assurance of safety. This can be accomplished only when no DCS incidents are allowed. A weakness of this acceptance rule is that a chance DCS incident might cause a safe procedure to be rejected. It is argued, however, given the historical precedent that decompression procedures are rarely too safe, that the probability of rejecting a safe procedure is smaller than the probability of accepting an unsafe procedure. It is further argued that much of the variability of decompression sickness which is usually ascribed to chance is rather a failure to ensure that the conditions of the trials duplicate the most severe conditions expected in the field.

Testing a Decompression Table

The testing of decompression procedures frequently involves validation of a large decompression table which contains many different schedules. It is usually impractical to test every schedule in a table, and a selection rule must be used to define a fair range of tests. One possible rule applies a factorial design to incrementally chosen depths and times. Suppose, for example, that an air decompression table were being developed for use down to 160 fsw. A 3 x 3 factorial design could be constructed around test depths of 40, 100 and 160 fsw and decompression times of 0, 30 and 60 min. When the schedules were released for use after validation, no dives would be permitted deeper than the maximum test depth, longer than the maximum bottom time at 40 fsw, or anywhere outside the bounds of the test matrix.

If 20 safe tests were required for each profile in the series, a minimum of 180 man-dives would be conducted. With 20 DCS-free tests, there is a 95% chance, according to the binomial distribution, that the DCS risk will not exceed 36%. With 30 safe tests for a minimum of 270 man-dives, the 95% confidence interval improves to 21%. A 4 x 4 factorial design would require a minimum of 320 man-dives with 20 tests per profile and 480 man-dives with 30 tests per profile. These are not an unreasonable number of tests, but if repetitive or multi-level dives were considered, a factorial design could require so many tests that some might have to be eliminated if the program were to be practical.

Selection of Schedules Using Likelihood

The selection of test dives might be facilitated by the method of maximum likelihood (15). Unlike the binomial distribution which is limited to trials of a single profile, maximum likelihood can be applied to an unlimited number

of profiles. This is accomplished by determining the best fit between a mathematical model and previous data. Maximum likelihood not only predicts a risk for a particular profile but might also provide a measure of statistical confidence based upon past experience. Testing could emphasize those schedules for which statistical confidence was low. If the full power of likelihood is to be brought to bear, however, it is essential that a large and well-documented body of decompression data be assembled and disseminated for wide use.

Doppler Bubble Detection

The initiating cause of decompression sickness is widely recognized as the formation of bubbles in blood and tissue. It is reasonable to suppose, therefore, that if bubble formation could be avoided, decompression sickness would be prevented. When ultrasonic bubble detection came into use in the late 60's and early 70's, the hope arose and was expressed in the 1977 workshop, "Early diagnosis of decompression sickness", that there might be "some way of diagnosing decompression sickness before symptoms developed" (16). This notion was consistent with the dominant Haldane decompression theory in which bubble formation and decompression sickness were simultaneous events (11). Accordingly, the detection of bubbles would be grounds for treating a diver and for rejecting a decompression profile. When doppler bubble detection showed that bubbles were frequently present in the absence of DCS, however, the Haldanian view led many people to reject ultrasound as of little practical value.

A further look at the data, on the other hand, suggests an alternative conclusion. Figure 2 shows the relationship between the precordial doppler bubble grade according to the Spencer (17) and Kisman-Masurel (18) scales and the DCS incidence for sub-saturation diving, altitude exposure, and saturation diving (19). The x-axis is the bubble grade which ranges from Grade 0 with no bubbles to Grade 4 with the maximum number of detectable bubbles. It is interesting to note that the doppler bubble detection capacity becomes saturated at Grade 4 and, in fact, 3 to 4 times more gas can be present in animals without disastrous results (20). The y-axis in Figure 2 is the observed DCS incidence at each bubble grade.

Bubbles are frequently detected in the absence of decompression sickness, and consequently, they are poor predictors of decompression risk. DCS is rare, however, when few bubbles are present. Indeed, Figure 2 gives an impression of the low risk end of a dose-response curve where the DCS risk rises sigmoidally from zero to one as the intravascular bubble volume increases. The absence of bubbles, therefore, is a good predictor of decompression safety.

A breakdown of 84 decompression incidents in Table 3 shows that 87% of all DCS was associated with intravascular bubble Grades 2, 3, or 4 (21). These observations strongly suggest that precordial bubble detection could be a useful adjunct in the testing and development of decompression procedures. If Grades 3 and 4 bubbles were disallowed, for example, these data show that the DCS incidence would have been reduced by an order of magnitude from 3.5% to 0.35%, and all serious symptoms would have been avoided.

Table 3. The relationship between doppler bubbles and DCS in 84 incidents (21)

Bubble Grade	0	1	2	3	4
Type I	2	9	11	29	19
Type II				7	7

Recommended Validation Procedures

In summary, the following guidelines are suggested for the testing of decompression procedures:

1. Define and control the test conditions. Do not exceed these conditions during field use.

2. Reject a schedule as unsafe if decompression sickness occurs.

3. Require at least 20 to 30 safe tests per schedule. Do not accept a schedule if decompression sickness occurs.

4. Reject a schedule as unsafe if precordial doppler bubble Grades 3 or 4 occur. For greater safety, reject on Grade 2 bubbles.

5. Use a factorial design to select schedules to be tested from a decompression table.

6. Use maximum likelihood to select schedules for testing. Omit schedules that are judged to be satisfactory by previous experience.

7. Use an IRB or similar review board for human experimentation plus signed and witnessed consent forms for all divers.

8. Separate the development and validation operational staff from the medical staff. The medical staff must have the right to take control of operations in the event DCS occurs.

9. Check insurance liability coverage is sufficient at venue for table testing at all levels. This should include coverage for the divers, development and validation staff and physicians.

10. Have informed lawyers check out all aspects of the planned work to ensure that all legal aspects have been covered correctly.

It should be emphasized that due to the unusual medical-legal climate in the USA today, human experimentation is most difficult. Testing of decompression tables will likely result in cases of decompression sickness. These may or may not be fully resolved by treatment. Then there are the long term risks of aseptic necrosis or other effects. For these reasons the consent form must be as detailed as possible as to the likely hazards of being a subject. Nevertheless all eventualities cannot be covered and one must be guided by the common standards for such research by one's peers and colleagues. For the present there can be little doubt that not only does human decompression table experimentation involve potential risk to the subject, there remains a very definite risk for the experimenter and his university or organization of having to explain his or her actions in court. Therefore, in conclusion, it is vital that all steps be fully documented in the planning, testing, possible treatments and medical tests, post dive follow-up etc. Such documents should be retained for a minimum of four years or whatever the statute of limitations may be in a specific state.

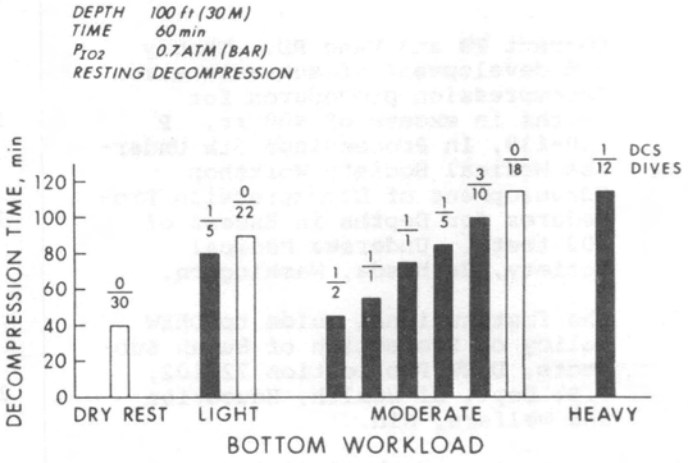

Figure 1. The effect of the dive conditions on decompression time for MK 15 dives to 100 fsw for 60 min (7).

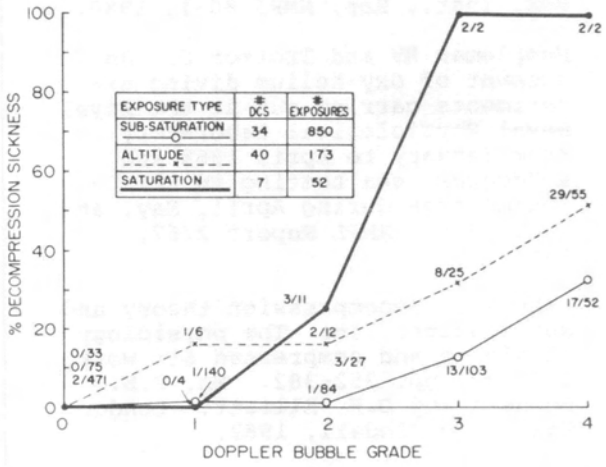

Figure 2. The relationship between doppler bubble grade and DCS incidence (16).

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DISCUSSION FOLLOWING DR. BENNETT

CHAIRMAN SCHREINER: That was the voice of experience speaking.

You are a very strong advocate, apparently, of the usefulness of bubble detection as an adjunct. How valuable is that adjunct in the experience of others here who have used it? Is there anybody here besides Duke that has actually used bubble detection for validation.

CAPT THALMANN: We saw most doppler scores on schedules which had been changed. We had a large change in incidence of bends, but the doppler scores overall did not seem to change very much. So, in that regard we are very sensitive. The data that Ron Nishi showed was only the first four dives; we have over 2500 that he has not seen yet. But the overall impression was that the doppler score was not really much more useful then clinical assessment after the dive.

CAPT HARVEY: I tend to go the same way that Ed has. We are not willing to make any of our tables based on the doppler at this point in time. The only thing I can say positively is that if I see a lot of bubbles, I have a high index of suspicion that I may see more hits from that table. I watch the diver--I will not say more concisely, but with more apprehension.

MR. NISHI: At DCIEM we do not treat on doppler bubbles. We take the occurrence of DCS as a criterion for treatment. We also see some funny things occasionally with the bubbles. We do have bends without bubbles, especially with oxygen decompression or even helium mixtures. So, there are some things to be resolved yet.

DR. BENNETT: There is no doubt that it is not perfect, by a long way. I wish it were. We need to have a good test before decompression--a prodromal test of decompression. Coming back to litigation, however, doppler has been around quite a while, as we are all aware, so if you do not use it, or at least have some other kind of quantitative indicator, you are going to have to explain in court why not!

DR. YOUNGBLOOD: One thing we seem to be skirting around here is that what the doppler does is detect the presence of gas phase in the blood. If your tables, as the "Haldanians" do, accept the presence of gas phase in the blood, then the doppler is not going to be a great deal of clinical utility to you.

DR. ARMER: The question I have is just for clarification. It appears from what I have seen here that Grade 1 and 2 bubbles seem to be of little or no predictive value. Is that so?

DR. BENNETT: We do not feel very strongly they have much value from the Duke point of view.

CAPT HARVEY: We feel the same way.

DR. KINDWALL: A question. It appears that one of the real problems we have is that their end-point, just like in the old days, is, "Does the guy get bent or not? Does he have symptoms?" That is very crude. Then we go to bubbles and then we have some arguments that are of little value. I would query if anyone is aware of any work using still other parameters such as platelet count, enzymes, filterability of blood, surface tension studies, and so on, which can be done postdive to evaluate or correlate with the incidence of decompression sickness. We tried tissue imaging--not doppler--which is a very nice laboratory technique. But it takes two years to get your first reading. It is very difficult to manage and is therefore not practical.

CDR HOBSON: We have some interesting work that has been started on immunological factors, specifically blood complement. We are in the preliminary stages, but we think it will show when you could be more susceptible. People that are more susceptible to decompression sickness have some nice correlations in some cases. On virtually every dive series that we do, now, we select three or four subjects and take a blood sample and do a complement. Then we can see how the doppler

and how the decompression stuff comes out at the other end.

Another one that was started but never really got off the ground was a force platform, a very sensitive platform that measured your center of gravity. Divers performed several predive maneuvers on this platform, and it drew a little sort of figure of how well they controlled their center of gravity. After they came out of the decompression, they went back in and did this same trial again. On a couple of cases where guys got hit, you could see hours before they had the bends; their center of gravity was off and there was something going on in there. It has not really gone much farther than that.

DR. KINDWALL: The problem with complement is that that is almost like preselecting your subject. On a given dive it is not going to tell you if you are going to get DCS or not. We are looking for something more specific to the tables.

CAPT THALMANN: One of the things with doppler that I would agree with is that if you look at high bubble scores and you have a high bends rate, as you reduce your table, the bends rate and high doppler scores go away. They tend to go away together. Now, that means the doppler is just subjective. Can you use the doppler to design tables where you never bend anybody? The answer is probably no. The point second of all is not so much as whether the doppler is useful in getting rid of tables which have a high incidence of the bends, because you can do that without the doppler.

But it might be useful in analyzing three schedules which have not produced any bends in 100 man dives and deciding which one is best. In other words, if you have a schedule with no bends, and let's say you make a change in the profile, is it useful in predicting whether you have done anything or not? That question has not been answered. Right now, you do not need a doppler to tell you somebody is bent. But they go hand in hand, as you avoid the bends, the doppler scores go down. It would be ideal if you could use the doppler to avoid bends altogether. I do not think it is there, yet.

DISCUSSION OF RESEARCH AND OPERATIONAL DIVE CLASSIFICATIONS

Russell E. Peterson, Ph.D.
Peterson Technical Service

I've been asked to present some views on the question, "When is it (a decompression procedure) operational and when is it experimental?" I've found giving a good answer to this question difficult, perhaps because there is such a high degree of subjectivity involved. I'll try, however, to point out the issues that seem important and my ideas about them.

In a scientific sense, a decompression is a research activity if it is being conducted to obtain information to add to the body of knowledge concerning such basic phenomena as inert gas exchange or the development of decompression sickness, or to aid in the evaluation of a novel decompression model or concept. Conversely, if a decompression is done with a validated procedure and there is no intent to obtain related scientific data, the decompression is not experimental, it is operational.

From another perspective, the legal one, Mr. James Sutterfield has advised me that a decompression would be considered operational if expert opinion held the schedule to be validated as safe, and experimental otherwise. Since expert opinion varies, this is far from a precise definition. It is closely related to the topic of this meeting, however, as to increase precision in this definition, we must establish what a validated decompression schedule is.

I believe the schedule may be considered to be validated as safe if there is direct operational experience which establishes this, or if it can be documented in standard scientific fashion through demonstrated principles and available related experience that the schedule is as safe or safer than other procedures in operational use.

I believe this latter approach to validation is extremely important to the continued development of improved decompression techniques. We've had a number of references in this meeting, already, to the high cost (in financial resources and time) of testing decompression schedules. If clearly conservative schedule modifications or procedure derivations are to be considered as experimental, with a laboratory test program then required as the first step in a validation process, the advancement of decompression techniques will be greatly retarded.

As an example, Dr. William Schane has used an established air decompression procedure for scientific air saturation operations at 47 fsw off St. Croix for some years. Despite the previous good record of this procedure from 60 fsw saturation depths, however, Dr. Schane considered the incidence of decompression sickness suffered by his divers to be unacceptable. He therefore introduced 40 minutes of oxygen breathing into the beginning of the ascent. This modification produced a marked improvement. Not only were cases of overt decompression sickness reduced (none to this time), but post-dive lethargy, which had been attributed to accumulated fatigue from the night watches and to the 16+ hours of decompression, was noticeably diminished as well.

I don't believe such a change as made by Dr. Schane should be grounds for considering that a new schedule is experimental and having to subject it to an onshore test program prior to field utilization. Established scientific principles of decompression tell us that such a modification will not make the schedule less safe. Thus, if it were previously safe enough for operational use, it should still be. Calling it experimental simply because it is different and untried in the new form would bring to a quick stop the dynamic field improvements that we have mentioned at this meeting - to the detriment of divers using the procedures. At least in diving related to offshore oil development, no responsible operator is going to permit a diving contractor to utilize what are termed "experimental procedures." I'm not saying that a modified schedule such as Dr. Schane put into use should be considered validated in a general sense. Since Dr. Schane considered the original schedule to be unsatisfactory at the time of modification, he would not have recommended use of it or his modified version to anyone prior to obtaining experience with the new schedule. From the standpoint of Dr. Schane's initial operational use of the modified schedule, however, that schedule was certainly validated. Now, with the establishment of a satisfactory track record, the modified schedule may be treated as validated for general use as well.

Another example of schedule modification, more extensive in this case, is the development of the so-called "Norwegian air tables" by Arntzen and Eidsvik of the Norwegian Navy. The approach they took was to consult with all the diving contractors using the U.S. Navy surface decompression procedures in the Norwegian sector of the North Sea, and to determine what the contractors' experience was with these procedures and what modification or modifications were in actual use by their supervisors in the field. Arntzen then recomputed the tables in metric unit by the same techniques used by the U.S. Navy for their initial derivation, but

with certain parameters modified to reflect or incorporate a sensible set of the field adjustments made by the commercial contractors. Though these tables were "new," they were actually closer to the real commercial field practice and more conservative than the U.S. Navy tables which were purported to be in use. Exhaustive testing of these procedures, as if they were experimental, would have been an extremely costly and lengthy process, if it had ever happened, and would have served to maintain less satisfactory and often ad hoc adjustments to the decompression practice. The treatment of these procedures as operation-ready, however, resulted in their rapid and successful deployment under closely watched and highly visible circumstances. A substantial body of good experience has now been accumulated with these procedures.

To conclude then, I believe that a procedure which can be documented as safe to the satisfaction of appropriate experts and in light of procedures in current use should be considered operation-ready. If these procedures contain more than very minor adjustments to schedules with an established track record, however, it would seem wise and responsible to initiate their use with a period of operational validation in which the divers were fully informed of the nature of the procedure and willingly used it. In addition, though this should be the case for all diving operations, special attention should be given to the provision of all hardware, supplies, and access to medical backup necessary for the proper treatment of decompression sickness. With respect to the documentation of dive results, I believe this, too, should be thoroughly done for all operational dives, not just those in a research or operational validation stage. The process of table improvement should be continuous, and this can be achieved only through the adequate documentation of experience. For procedures that initially cannot be adequately documented as safe, and as such must be considered experimental, I agree with the general approach of a laboratory test program with full research safeguards, followed by a careful introduction into field use.

Finally, before discussion of this presentation begins, I would like to put two questions before the group. Is validation/evaluation of a decompression procedure ever finished? If so, what is end point of such completion? As stated, it is my own opinion that the evaluation of decompression procedures should be continuous and on-going for as long as those procedures are in use.

DISCUSSION FOLLOWING DR. PETERSON

CHAIRMAN SCHREINER: Thank you, Russ, for a very clear exposition of diving technology transfer. How do you get it into the field? I think that as in all intellectual processes, semantics is very important. Call something "experimental" and people are concerned. Call it "provisional," and it might not have the same impact. Yet, you have clearly distinguished it from an "operationally ready" or "validated" label.

GENERAL SUMMARY AND CONCLUSIONS OF THE WORKSHOP

H.R. Schreiner

CHAIRMAN SCHREINER: So, I see as one of the tasks that will remain to be addressed after this workshop is a nomenclature to allow effective communication.

Now, I would like to give you an analogy from my industry, where clinical instrumentation is developed which ultimately has a direct effect on human health and safety. It may be useful to convey to you how we research, develop, build and put clinical instrumentation into actual operational use.

In our nomenclature, we start with feasibility. We do research to determine whether and how major design objectives of a new concept can be met. That might be a decompression model for doing useful work at 600 feet breathing neon-oxygen, for example, where in the diving equivalent it would call for animal studies.

From that point forward, we put together a breadboard, which is an assembly of all the pieces needed to put the concept through its paces. That would be analogous to human table development in the lab. And then we proceed to engineering prototypes which begin to look like the finished article. It may have the wrong color and it may have the buttons in the wrong places. That would be equivalent to what one may call a "provisional" decompression procedure. In any event it is no longer "experimental."

What follows in my industry is pre-production, which means the new product is ready for operations. That is, we are going to make those instruments in the plant by blueprints, by procedures which the plant accepts. In the diving case, it would be the commercial operational management or the commanding officer in the Navy who accepts the procedure for operational use. And only after the product is actually being manufactured do we do what we call "de-x" the blueprints. The blueprints are originally marked with an "x" saying they are ready for operation but not yet validated.

Only after, say, six months or maybe longer in actual operation do we de-x blueprints. We are then dealing with a validated product that is being made by the thousands. Maybe we should think in these terms and find appropriate nomenclature to designate the equivalent distinction, in diving terms, between feasibility, breadboard engineering prototype, preproduction, and production. Maybe one of the fallouts from this meeting could be a consensus statement as to how we distinguish between these stages.

And I agree with you: Validation never stops. This is equally true in industrial experience. Once you make an instrument, the competitors will do something that will force you to update it, to do it better, to do it cheaper, to do it faster. So our responsibility for diagnostic instrumentation never stops, and neither does the responsibility of the decompression community for bringing about better, safer, more efficient decompression procedures.

DR. HAMILTON: If validation never stops--I agree that it does not--at what point can we stop having the divers sign informed consent statements?

CHAIRMAN SCHREINER: From what I have just heard, I would say at the point--which has yet to be defined--that is called "ready for operations," or when you are out of the "breadboard" stage. That has to be defined.

CAPTAIN THALMANN: One of the problems that has kind of gotten blurred is the distinction between developing new procedures and what you might call table modification. I do not think anybody would ask a diver to sign a consent form if you decide to add a little shallow oxygen to reduce your bends score.

The Navy was having problems with the saturation excursion schedules. We sat down, and within 12 hours said, "Do it this way." I mean, we did not do any more man dives or anything like that. Everybody agreed that this was a conservative adjustment. I really wonder if companies can get into trouble if dive supervisors empirically try to adjust tables to make them safer by either lengthening stops or adding O_2. The problem we

are talking about is somebody going out and developing a new procedure, doing it totally differently.

DR. LAMBERTSEN: One simple point. I would not expect supervisors to have that role (to make a new procedure), or even diving companies. I would like to think that somewhere in the evolution of the tables, there would be the pulling together of some people with the right background to be able to make a change authoritatively so that it would be accepted instead of being argued about by the rest. You did that. You did not pull a bunch of uninformed people together. You pulled together a small group of informed people to make that decision. That is what we have to do elsewhere.

CAPT THALMANN: Yes, but diving supervisors do it all the time. You know the procedures allow them to do that.

EDITOR'S NOTE: Two points seem to be under discussion simultaneously, (1) the development of new procedures, and (2) conservative modifications made by a group of experts or in the field by a diving supervisor.

DR. LAMBERTSEN: That is very important. What I am trying to do is put a bridge in between what Dr. Peterson said and the alternative, so that wherever this development is happening the system ought to have the ability to pull in individuals who have a capability for helping, whether in the Navy or in a corporate body or somewhere else. They do not have to be the same people across the world to do this, but you have to lean on more than one person or one place that has an authority.

CHAIRMAN SCHREINER: The authority has to be fixed. I mean it has to be clearly understood who can and cannot make those decisions. Dr. Shane added oxygen breathing during decompression; he obviously made it safer and obviously cannot be faulted for that and, in fact, he had improved results.

However, I submit that if you were to say from now on, "Use oxygen at x meters," that procedure in my mind has not been validated until you actually have done it under operational conditions and sufficiently often to say, "I have actually validated ["de-xed"] this apparently safe and sensible modification." So, I do not think you could ever validate something without doing it. I just want to make that point; I hope you agree.

DR. PETERSON: Yes, except that what we are talking about is whether something is safe or not. Oxygen has two effects. One is to reduce gas loading and the other is oxygen poisoning. This was a situation where the oxygen exposure was so low that there was no need to consider that as a problem. From the gas loading standpoint, it certainly was not going to make the situation any worse. And the procedure was already in operational use.

CHAIRMAN SCHREINER: My comments are just a semantic clarification, not that I question what was done. I think the term, "validation," the verb, "to validate," has to be reserved for activities that actually expose a human being to a particular operational condition. I hope we can agree with that definition, that validation can never be done in theory. It has to be done hands on. Is that correct?

DR. KINDWALL: At what point do you allow that change to be made, as in Bill Shane's case, without having the diver sign a consent form? That is the practical point.

CHAIRMAN SCHREINER: Well, that is a good question. If you do something which, in the view of people experienced and knowledgeable in the field is a safe step, a safe addition, I am not saying that it should not be done. But that does not mean it is validated; validation is the result of successful operational use.

Is it experimental?

CAPT THALMANN: No. It is a point that has already been validated: That oxygen shortens decompression.

CHAIRMAN SCHREINER: Under these conditions?

CAPT THALMANN: Yes. Under any conditions. You can get literature to show this. But you have to validate something that has not been shown.

DR. LAMBERTSEN: Heinz said validation--I guess the word means somehow seeking the truth--has to involve the human. But it does not have to be prospective. It can also, as Ed has just said, be retrospective if you already know the truth. If you do not know the truth, then you have to get together with a bunch of people who help you pin it down.

MR. HOLLAND: Who makes that change or that validation? Does the diver in the field or the supervisor have the authority to do that? Or is it done some other way? If there are going to be changes made to procedures they should be by those people nominated in a company who decide on whether that change is to be made. But it is not sufficient just to have done that, it has to be put in writing, with the reasons why you have done it. In other words, you have to give some form of authority to the fact that it was done; otherwise, you are suggesting that people can be changing things all over the place. In each operational area, you could have people doing things differently. So, you can have a system within a company where you do not allow things to happen unless they are put in writing. Each company will have its own expertise, and it will be signed off with its reason why it is being done, and then circulated as a document to support the change, making it legal.

DR. KINDWALL: I want to relate this excellent discussion to another area: What is experimental? Right now OSHA is faced with a difficult decision; perhaps this group can help. It has been known for many years that oxygen is very efficacious in reducing the bends rate. But if it is used in an industry where it has not been used before ever, is that experimental? Second, should the people using oxygen decompression be asked to sign an informed consent? In other words, will that make people nervous, and is that useful. Will that delay its acceptance. That really calls the question whether this makes the whole concept experimental.

DR. ELLIOTT: The definitions in the Helsinki Convention, I think, are quite clear as to where consent is required from experimentation. Surprisingly, it appears to be not so much the content of the change as is the purpose of the change--in that particular case, the dive that you are doing. If you are a reasonable authority and have decided that you need to test, then that is human experimentation and requires a consent form and so forth. But if a reasonable authority decides that on the basis of historical experience that what you are doing is not a test, then it is an operational evaluation and you can go ahead. It is not an experiment, you do not get consent forms, etc.

The essential difference, became very clear to us in our work in Norway. If you are following the Helsinki Convention, it is for the purpose--officially--of scientific research and publication and it is under the overall direction of some medical person, then you need informed consent. There is no way in the field, the field modifications and so forth, where you are going to be anything but in the charge of somebody who has executive authority over the dive, not a medical person. Therefore, in my mind there is quite a clear boundary between what requires human consent for testing and what is, in fact, an operational development.

To summarize, the Helsinki Convention looks at the purpose of the activity. If it is being done for the purpose of scientific research, the purpose of publication of papers and so forth, then the responsible authority must go through the business of getting consent and must also have a medical person responsible for what is going on.

If, however, on the basis of historical evidence, the responsible group agrees that what is being done is a reasonable activity and if that activity is for the purposes of a job of work which may include operational evaluation, then that dive--and this applies to many of the dives at sea--will be under the control of a diving supervisor, not the doctor.

If I may also use an analogy, one in fact that I used in Norway and which helped us to crystalize this. For example, take a test pilot. If you give him a psychological questionnaire about his sex life, that done in a research context requires Helsinki consideration, ethical approval, the whole bit.

If you tell that test pilot to get in that airplane and it might crash, that is a high risk activity, but it is not medical research.

CHAIRMAN SCHREINER: That is, you distinguish between experimental and operational by intent.

DR. ELLIOTT: By intent, yes. But by a responsible authority.

MR. GALERNE: Let me give you a little point of view of the contractor.

A long time ago in 1964, we developed some decompression tables for operational review. We have a device which records all of our dives on graph paper. Every time we have any problem on the job, the crew chief is obliged to mark where the problem started and what action he has taken. We have done that thousand of times.

We have magnified slightly those charts. For example, at one time, we had problems with our deep dives. We felt it was in going back from the bottom to the first stop. I decided we could stop at 2/3 of the first part of the ascent and make a new stop there for a few minutes and see what would happen. We increased or decreased the time of that stop a few times, but at the end, by a slight modification like that, we succeeded in getting tables which caused very, very few problems.

But, if you try to make something scientific of my tables now, you will have a lot of problems, because a lot of things have been done--increasing that stage, moving that position, and so forth. These things have been done to make them work, looking at the data and making some decisions saying, "Well, we will try that."

Now, it would be difficult to make a "model" for all those tables, but they work pretty well. So, can not say if it is experimentation or what, but it is a practical way to do it.

CAPT HARVEY: I am always reluctant to do anything Dr. Lambertsen says, but he taught me to do that when I worked for him, so I shall.

Sometimes perhaps truth is like the elephant. I am not sure whether I am seeing a rope or a tree trunk or the side of a wall. So we must avoid the pitfall of truth being what we perceive, and therefore go charging ahead madly on partial truth.

If someone had asked me, "If you switch to air following a helium deep dive, would you get a vestibular hit? You are going to air, which has more oxygen and nitrogen, and is a slower gas." Knowing what I do about isobaric gas exchange, etc., I would have predicted that you would not. But from one of the testimonies today, it happened. I feel very strongly that predictions of what you think is going to happen must be tested.

I think that in terms of tables that are going out into the Fleet, there are different categories of tables. The degree of risk and, therefore, the degree of attention and the degree of support they must have may vary a bit with how they were derived.

Ad hoc tables that have no real sound foundation, simply that somebody wants to see what will happen (as Haldane did), obviously are a bit more risky.

The next category, perhaps, might be new tables based on proven models, where the model itself is obvious and has been evaluated. That is a bit less risky. You can evaluate the risk better.

Then you can have tables that have been proven, but have been modified. For instance, you have added oxygen. That is not a major modification in the table. It is a very logical extension of our knowledge. I consider that a far less risky table and, therefore, think we can accept tables in that category.

Finally, you have the ones that have been proven elsewhere but are being reformulated in some new write-up technique or something of that nature where the table itself is basically sound. It is simply being adapted for your use or adapted from someone else to your particular commercial company. That is probably the safest of all categories.

I think you must not lump tables and simply say they are new. There are categories of newness.

CHAIRMAN SCHREINER: I agree with that.

DR. YOUNGBLOOD: I want to address an area that I think we are slightly missing here, an area that Andre and Dutchy will certainly appreciate. Let us address the area of the diving supervisor's

prerogative to modify the tables on site. With all due respect to Dr. Thalmann, I think there is no commercial diving company in the world that exercises the degree of operational control over their supervisors that you may think exists in the Navy (I hope it does exist). The diving supervisor, although he may be experienced in the techniques, is a layman in medical and physiological concepts and may be a victim of what I call the "more is better" concept, whether it is Vitamin A or whatever. One of the statements we have made is that it is always all right to add more oxygen or more decompression time. That is not necessarily so.

I can recall a very concrete example of a well intentioned diving supervisor faced with an operational situation with a modification of a modification embellished with another company's modification of helium-oxygen surface-supplied bounce tables, who decided that you might as well add some deeper stops and add more time, since more decompression is always better. It turned into a clinical disaster. And that is the kind of situation which I feel that we should somehow go on record as recognizing as not safe, adequate, moral, or ethical.

CHAIRMAN SCHREINER: That is fair. Let me see if we can crystalize something here, because it has become abundantly clear over the last two days that never, ever would the U.S. Navy, the various industrial companies both here and abroad, the foreign navies, the foreign governments like the Canadian Government, join forces in some kind of unitary global way. This will not happen.

We have to recognize that each diving community--and it could be that NOAA is one, the Navy is another one, etc.--will have to seek its own standards of conduct. We recall yesterday's summarization, experience leads to incremental advances which lead to more experience which leads to improvement in safety and efficiency. There are clearly global standards because human beings do not differ all that much across the various constituencies.

So, fundamentally, there are immutable physiological and physical considerations that are no different anywhere in the world. Once that is said, then I think each group--in fact, each company--ought to be encouraged to have a means of insuring decompression quality. I just use this for lack of a better term.

If you wish--and somebody mentioned it a little a while ago, maybe it was Dr. Lambertsen--an internal group of knowledgeable people should be installed who will, for example, in the case of the dive supervisor, establish the limits of that person's authority to make procedural changes within a certain variance. Beyond that the supervisor would have to get emergency support if situations were to arise that go beyond the limits of his authority.

However, I think while there are standards that a group of knowledgeable people can develop and recommend, worldwide, really, for all diving, each diving community, in my opinion, would have to take their basic recommendations and translate them into operational control over the quality of decompression in their particular group.

How does that strike the group as a consensus statement or the beginning of one?

You were about to tear something up, Commander. You had a piece of paper in your hand. Your body language--

DR. WEATHERSBY: It was a draft of an international agreement between the American and Canadian Navies to work together towards a joint set of decompression tables.

CDR HOBSON: That is one thing in that summation statement that I have to disagree with. I think there is a will, and today, the only way that things are going to get better it is with this type of exchange of information, this type of meeting where there is free exchange and people start breaking down these barriers and sharing experiences.

CHAIRMAN SCHREINER: You misunderstood my intent. No way do I wish to compartmentalize information.

CDR HOBSON: No, no. But your opening statement was that you did not see that is it possible in any way that the navies of the world and the commercial companies of the world and the various scientific units could get together in one sort of global agreement.

CHAIRMAN SCHREINER: Well, what I meant to say, perhaps I did not say it properly, is this: It is illusory to believe that a unitary set of rules binding on everybody could ever emerge.

CDR HOBSON: Okay.

CHAIRMAN SCHREINER: I think that could be a consensus statement. By the same token, there are immutable physiological and physical laws that apply to diving and they apply to all diving communities. And basic standards of safety, basic vocabulary, can be common. Once those are in place, then each diving community looking to that commonly agreed to basis of what is reliable decompression, what is required to go from A to B, from experimental to operational, can then in its own jurisdiction develop procedures approximate to its mission.

I cannot imagine for example that the United States Navy would listen to an external body to change its command structure or its way of operation. That is not for us to propose. We are not here to dictate. But I think we can find common ground, make common recommendations to all diving communities which in turn can be translated internally into procedures which will make their operation safer and more effective, not the least by sharing information. So I hope there is no disagreement on this point.

DR. LAMBERTSEN: Even if their missions are different, that still pertains, and the mission will be different all of the time.

DR. KINDWALL: Part of your remark was the implication that this Workshop should recommend that a consensus group within each company or navy or so on be tasked with the idea of making changes in tables and keeping then abreast. If something is wrong, then this particular group would address the issue and fix it. Does that imply then that any set of tables used by any organization should automatically have a built-in capability for modification and review as an ongoing thing? Is that what you meant to imply?

CHAIRMAN SCHREINER: What I meant to imply is that we should strive for a consensus on basic fundamental definitions, the foundations of safety, of validation, so that this becomes a commonly accepted body of codified knowledge from which each group derives its own operating procedures with reference to a common set of standards.

DR. KINDWALL: Would you wish to say anything about the concept that there should be a mechanism for change?

CHAIRMAN SCHREINER: Yes. I am sorry if I implied some kind of rigidity here. I think that if, for example, if such a group of experts were to agree that a reliable decompression is one which by statistical probability X creates result Y, that this is a criterion. That is not standing in the way of change. That only defines what the community means by a successful decompression procedure.

DR. KINDWALL: As it is now, for example, the French Navy, the German Navy, or the U.S. Navy could have a table, and it may be well known that there are better procedures elsewhere, but the existing procedures are not easily modifiable. We should then make a recommendation that if you are subjecting human beings to known hazardous decompressions, then there should be a mechanism within the organization for improvement when it is needed.

DR. ELLIOTT: I have done a little diagram (Discussion Figure 1) which I think summarizes pretty well what we have said. We do not have time to discuss it or put it up on a flip chart. Can I just offer it to you and to Bill Hamilton to consider for the proceedings. There should be nothing that is too controversial there. It summarizes roughly what I understand to have been said here.

Having said that, can we also be a little bit more practical? I think there is one consensus statement needed, of greater priority. That is the importance of the collection of field data and feedback to the responsible authority (whether that be in the diving company or at some national level, I believe is not important). I would personally like to see that. We have a lot of operational data. The dives may not necessarily be done in accordance with the way the tables are printed. That is very valuable data. It is also of some secondary value too in the assessment of the bends that may

arise subsequently. I would like to see that as one of our consensus statements.

CHAIRMAN SCHREINER: I think this was certainly said yesterday, but was further made practical today because the maximum likelihood approach or similar approaches that permit the retrospective extraction of valid data from dives which have already occurred. If the same information can be obtained in that manner, as can be obtained by additional exposure of humans to decompression conditions, I think it is not only useful but a more ethical way to lay on ourselves the opportunity for change.

DR. ELLIOTT: The quality of data may be critical. You could only do some types of analysis under laboratory conditions. I would like to see the probabilistic theory applied to operational diving, providing, of course, one has the pressure and time correct. Is it possible? Dr. Weathersby, are you prepared to state what are the things which one must have to make your type of analysis, as far as you are concerned, acceptable?

DR. WEATHERSBY: Only partially. Part of the answer depends upon the use, which is not yet specified. The model that you try tomorrow may have different requirements for data quality than the model I used yesterday. So, as a general statement, make it as precise as possible to be as generally useful as possible. But, certainly, the detailed record of pressure, time and gases and a detailed record of any medical outcome (whether or not there was a treatment) would be basic components.

CAPT THALMANN: I think what it boils down to is that in the commercial industry there is no formalized method of getting things changed. Within the military there is. That is what makes it easy. There is a mechanism for instituting a change very rapidly, if need be, because there is some guy who has to sign his name on the line saying, "I have responsibility for all these people, and therefore I say we are now going to change this procedure in this direction. Period." And it gets done.

For instance, just recently, within the Royal Navy we have been making minor modifications to the saturation decompression without anybody signing consent forms because there is a mechanism. I submit a proposal and it is reviewed by RN people. They say, "We agree, this is not a significant change and it is in a conservative direction. Therefore, you can take it out on a ship and try it on an operational dive under the conditions put forward."

The problem is that in the commercial world there does not appear to be such a mechanism. It exists in the U.S. Navy in the sense that the Supervisor of Diving is the guy whose name is on the line. The same mechanism exists in the Royal Navy. But there is an individual who then is responsible for ensuring that all the "experts," have made the right decision.

But, commercially there is nobody to say, "Look, I want to change this procedure. Is it okay to do it? And I have six people (the "experts") that say it is okay."

CHAIRMAN SCHREINER: Yes. But there is no reason why a diving company cannot institute internal procedures that parallel those of the Navy.

CAPT THALMANN: There should not be, but it seems to be the case.

MR. GALERNE: I think a general step we can take would be to have a recorder assigned to each company to record all the data of each dive, and have the data go to a computer something like that where we can exchange the data without having to retype it.

We do not have a regular interaction. Maybe that would be something to do, to develop a common support for industry where we can talk together about some data.

MR. IMBERT: You should not underrate the capacity of the commercial industry to evaluate and adapt and improve its own procedures. Look at the work reported by Mr. Humphrey, for example, or ours.

Definitely there is a will and a means and the expertise in the commercial diving industry to improve procedures for better and safer diving. We are the only ones to take our own fate in hand, because we know exactly what we want and what we have to work with. We have different

needs from the U.S. Navy. Even though we have less money and fewer people, we can organize ourselves to get useful data. You should leave room for commercial diving to take care of itself.

CAPT THALMANN: You should. Even so, I sense there is a frustration that the commercial people have the impression that they somehow cannot. Is that a reasonable frustration?

MR. IMBERT: The important thing, I think, is that there will be new tables. We have to take some risk sometime, and there is no excuse for not being well organized. That would be the key point to discuss. But I think we are a people who are professional and responsible.

The lack of organization is not acceptable. We should control ourselves. In a well organized diving company we think we have good control for a given dive, like any other group. I think that is really the case in the commercial diving company that does serious work.

MR. HOLLAND: I do not think the frustration exists in the ability to react to situations. I think we react to situations probably very quickly. We continually monitor things, and if something goes wrong, we can do it and we can get something moving probably as fast as anyone else. I think the frustration exists in the fact that we would like some sort of guideline that would help us to justify what we are doing. We are going to do it, whether or not we have a legal risk. We have to do it in the absence of guidelines at the moment, or validation parameters. My frustration is that we do not have anything to help us to do that. But we are still going to do it and do it quickly.

CAPT THALMANN: Well, I think that was the point I wanted to make. The military has the organization set up to do that, and I do not sense that there is such an organization in the commercial field.

DR. LAMBERTSEN: Let me add to Dr. Schreiner's effort to put some general things together. We have the opportunity to look back at what Dr. Elliott called a mass of useful data that is not as useful as it could be because it has not been generated as data. We have an opportunity to improve upon it by generating a proper means of recording in advance so that we will someday have that as retrospective data. I would like to see worked into the general principles a goal of improving upon the quality of the data obtained in the validation process.

CHAIRMAN SCHREINER: Right. Now, I would like to ask that is it not inappropriate, perhaps even unethical, to ask a diving subject to sign an informed consent, expose himself or herself to risk, become an experimental subject, without maximum information and use being derived from that exposure. The only way to do that is to record properly the experience. That is done in the laboratory, no doubt; but, then, I am not sure whether the information is accessible in a way that others can benefit from it. I think you are asking for a uniform way of recording and reusing and re-examining diving data.

DR. LAMBERTSEN: If not uniform, at least compatible.

MR. GERNHARDT: One thing that we were about to do that I think would help the commercial companies with respect to the legal aspects was to define, subject to interpretation by the responsible individuals, exactly what experimental, provisional, and operational areas are. Recognizing that there will be some interpretation, nevertheless, it would give us more guidelines than we have now.

DR. ELLIOTT: I think I can answer what has just been said here. One of the things from the diver's point of view, as opposed to the intent of the people instituting the dive is, is it part of his job description to do it? That is a very practical point. It is like a test pilot, again.

CHAIRMAN SCHREINER: I think for the commercial side that would really have to be sorted out on a company level.

CDR HOBSON: I think this is a very important aspect of what we want to do; however, I strongly support Captain Harvey's point that there are different categories of change, and what we have been getting trapped in occasionally is that we are

talking about bringing the big sledge hammer for a lot of these little piddley bits.

What we should do, I suggest, is a categorization. The worst case would be if you have just discovered you are going to have tables based on plutonium. We have talked about what you have to do to get it out in the field. At the other end, how the small changes, the operational changes, get accepted and get this magic "validation" to give the commercial companies the needed confidence, should be in a lesser category.

CHAIRMAN SCHREINER: A point well made. To go back to Dr. Elliott's diagram (Discussion Figure 1), he shows how we need to think about new models, which is, an extreme case. But I would also submit that any changes in a decompression procedure should be made only in accordance with principles that a group like this or a small subset has developed as guidelines. Some of the changes can be made in operations; operational modification, operational improvements. Some of them will require at-sea trials of some sort. Some will require experimental work in the laboratory on men, or may even go back to studying a new decompression model in animals.

But, in any event, I believe there has to be consensus. I am sure this group will agree that criteria should be proposed by a small group of experts in the field that say: Here is what we would consider reasonable and prudent for someone to do to get from this particular category, experimental, to the category of operationally ready, to a category of operational modification, etc. I do not want to put words in mouth of the group. Is there any disagreement with that approach?

CAPT THALMANN: I do. For an example, I think that the FDA does not tell people how to test a drug, but they do tell them what documentation they have to plop on the committee's desk before they can decide whether it is okay to use it. You have to look at the difference between table validation criteria. All you can agree on here is how to tell people how to go about gathering up data they will need to substantiate a change, but not tell them what the criteria are, because I do not think anybody could agree on them. Certainly, within the Navy, the criteria change as experience is gained and new people take over.

Right now, when a new table is set up certain individuals with certain biases read it and decide whether or not they think it is reasonable to recommend that this procedure be accepted.

CHAIRMAN SCHREINER: Maybe we can get this discussion focused by not speaking of criteria but of standards.

CAPT THALMANN: How? What is required? What documentation? What methods are required in order for you to justify a procedure so the individuals can decide?

CHAIRMAN SCHREINER: Those are standards, because when you talk about criteria, the Navy may use different criteria from the next diving community.

CAPT THALMANN: They change. The criteria change.

CHAIRMAN SCHREINER: Yes. I accept that.

CAPT HARVEY: We sit here because of legal, ethical and financial pressures that drove this group to exist. We got hung up on the ethical thing because that reflects the legal pressure that in the past have cost lots of people lots of money.

It seems to me that we have gotten around the problem of using human subjects and the legal complications that can come from that by having informed consent. I therefore feel that the use of informed consent, for people who have less than validated tables (whatever our validation criteria) is both ethically and legally a very sensible way to go. If the guidelines of this workshop can include "informed consent" for the people who are using less than validated tables, we may solve or at least help to solve some of their legal and other implications. I do not think it will be a complete shield. An informed consent document is not worth the paper it is printed on if there is negligence. But I still think it is both ethically and legally sensible to try to call for informed consent when you are developing new tables in the field situation.

EDITOR'S NOTE: Capt. Harvey later agreed that informed consent was only necessary in the testing situation.

Tables furnish statistics. When I was with Dr. Lambertsen at Pennsylvania, we were establishing a thing called the International Decompression Data Bank with the very idea of keeping enough baseline data in carefully controlled experiments so that it would be available to the world to be used as a basis for the kind of comparison that CDR Weathersby has been doing.

I would submit that if we all used that mechanism (accumulating dive profile data for retrospective analyses), whether at Penn or otherwise, it would give us the baseline data we need to validate tables.

MR. IMBERT: I just want to make an analogy. With deep diving, as technology was 10 years ago, when the contract came you could not dive deep because the equipment was not ready. So, in the 1980's, there are a lot of published standards for equipment performance and how to test it. We have regulations, procedures, criteria, etc., covering equipment, and the standards are generally accepted. There is a possibility for modification of the process. I think this may be what is happening now in decompression. We have come to a point now where we have data banks available, can study the information, and we have tools, like statistical analysis. I think it is time, now, to issue standards or criteria to test and evaluate decompression. That would allow tables to keep improving, but we will at least have a standardized way of discussing and comparing results.

CHAIRMAN SCHREINER: I think that would be a very useful outcome of this group's effort.

I would like to ask Dr. Elliott to lead us in a discussion of his diagram.

DR. ELLIOTT: In the diagram I have divided the process, by the waves of the sea, into two areas: Academia and the Real World.

Note the "by intent." Is the intent of what we are doing research and the furtherance of knowledge, or is it operational and part of the diver's normal job description?

Kindly note that this does not relate to risk. Risk can be high on either side of that boundary. And it obviously must start with a new model and table calculation and the testing of the table, possibly in the sea.

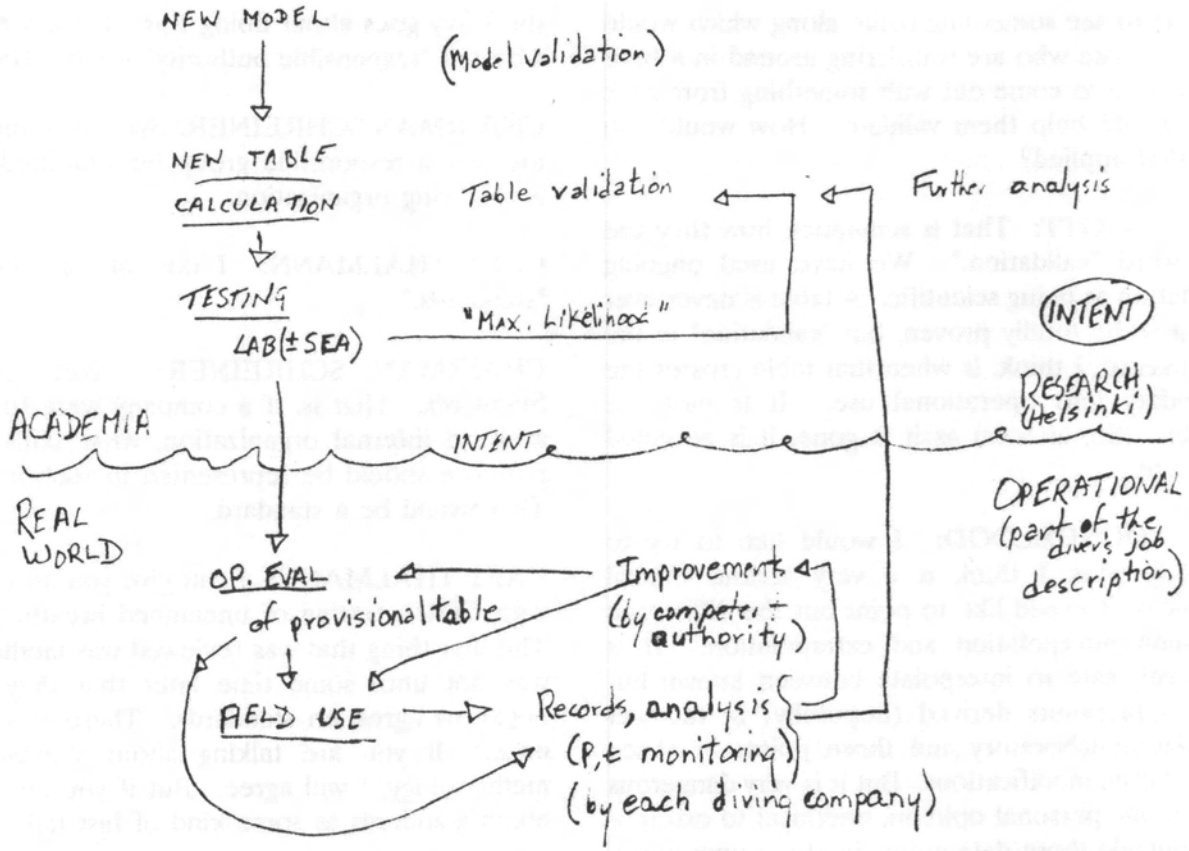
In practice, the Navy is the only group to cross this particular boundary. One or two commercial companies have done so as well, and perhaps others. But I think it is easy, with both the Navy and with Comex, to distinguish between the intent of a particular dive. One then gets to the operational evaluation of the "provisional" table. It is something based on experience and it is considered by the responsible authority to be an acceptable procedure when it is complete. The normal diver can do it under normal conditions. The feedback from the provisional and the subsequent field use is the area which I think this meeting can lead to the greatest improvement of knowledge.

As Ed Thalmann said right at the beginning, you know, the bloody Navy never gets any feedback. So, let's get the feedback organized. If we can use maximum likelihood on the feedback, great! But if the data is not quite that good or that voluminous, it is still good feedback. The feedback then goes back both to the diving company's own authority (whatever that might be, and I think some criteria for that might be appropriate). Or it could be at the national level. It does not matter. But there is feedback, so improvements can be made during the use of that table. Further feedback, of course, goes back to the original authority, because, as we have said, and somebody has made the point, that table validation is never over. That is why I drew my breath in when someone said, "informed consent while we are going on for validation." I have drawn it to say, as soon as we have finished the testing, then informed consent is no longer applied.

CAPT HARVEY: Informed consent for testing, then, perhaps is better.

DR. ELLIOTT: Yes, fine.

CHAIRMAN SCHREINER: We still have a few more minutes, but I would like to make sure that before this meeting closes, there is a semblance of



Discussion Figure 1. Sketched diagram proposed by Dr. Elliott. The top part represents the laboratory or "informed consent" zone which is experimenal by intent, while the bottom part is within the job description of the diver. This formed the basis for Summary Figure 1, found in the Editorial Summary, which includes additional ideas, especially the role of a competent authority in making the decision when to move to provisional and operational use. (Retouched for readability.)

consensus. Therefore, I would like to test the group by saying: Is there anything that Dr. Elliott has drawn or said that anyone in this room would take exception to? If so, please make that known now.

DR. KINDWALL: I have a brief question. Supposing someone like Global Marine or some big company that is still in business wants a decompression table for a special job. He goes to someone like, say, Pete Edel, and asks him to draw up a table and he does and it looks good. Where does that fit in? They want to go and use it operationally, and they go ahead and do it.

CHAIRMAN SCHREINER: Well, what you are doing is you are transferring technology from the laboratory to the real world. There have to be standards by which the user, which would be the diving company, can decide whether to accept this technology.

DR. ELLIOTT: I think it is a question of whether Peter Edel is modifying an existing fund of knowledge or whether he is sticking his neck out a bit; that is the decision of the responsible body.

CHAIRMAN SCHREINER: The readiness or the ease of acceptance would depend on the nature of the quantum incremental change. In any event, we would urge any diving community to have an internal mechanism, perhaps through outside experts, to judge whether a proposed procedure is ready for operational use.

MR. HOLLAND: Some of this seems related specifically to the U.S., but I mentioned a problem we had in the UK on validation of tables. I was

hoping to see something come along which would enable those who are wandering around in a haze to be able to come out with something from here that would help them validate. How would you see that applied?

DR. ELLIOTT: That is semantics, how they use the word "validation." We have used ongoing validation as being scientific. A table is never ever going to be totally proven, but "validation" in the legal sense, I think, is when that table crosses the boundary into operational use. It is past the border. So, as soon as it is gone, it is accepted into use.

DR. YOUNGBLOOD: I would like to try to simplify what I think is a very serious ethical problem. I would like to point out the difference between interpolation and extrapolation. It is relatively safe to interpolate between known human data points derived (hopefully) in the wet simulation laboratory and those points in at-sea operational modifications. But it is very dangerous and, in my personal opinion, unethical to extrapolate outside those data points in at-sea operations.

DR. PETERSON: I would like to agree very strongly with David's statement.

CDR HOBSON: Improvements are limited to interpolation only.

CHAIRMAN SCHREINER: We are now discussing standards that another group, hopefully, will recommend in detail. And these are elements that should go into these standards.

CDR HOBSON: What we want there is a feedback loop. It should not imply that maximum likelihood has to fit into this process. It is just a feedback loop.

DR. HAMILTON: Then I request the adjective "quantitative," if nothing else.

CHAIRMAN SCHREINER: The feedback process should be quantitative.

CAPT THALMANN: I think what Dr. Elliott has drawn is a flow chart that probably is exactly how the Navy goes about doing this. He has not said who the "responsible authority" for the Navy is.

CHAIRMAN SCHREINER: We are recommending that a responsible group be identified within each diving organization.

CAPT THALMANN: I do not like the word "standards."

CHAIRMAN SCHREINER: Not "criteria." Standards. That is, if a company were to set up such an internal organization, what skills or experience should be represented in such a group? That would be a standard.

CAPT THALMANN: I can give you an example with EDU's testing of unmanned breathing gear. The first thing that was reviewed was methods. It was not until some time later that they finally began to agree on standards. There is a difference. If you are talking about standards for methodology, I will agree. But if you are talking about standards as some kind of fast fail. . .

CHAIRMAN SCHREINER: No, no, no. I backed off the terminology "criteria," because you objected to its rigidity. And substituted the word "standards" to be synonymous with methodology.

CAPT THALMANN: Okay.

CHAIRMAN SCHREINER: I do not want to go further and dilute the word "standards," because if we can not agree that standards are needed, then we are really just blowing a lot of wind. We should do more than just discuss the subject.

Standards should mean procedures by which diving communities can arrive at decisions that will guide them in determining when a decompression procedure change is appropriate and when and how it should be tested or evaluated. That is what I mean by "standard." Is that agreeable to everybody?

It is exactly 1400 hours. I declare the Workshop closed. Your editors will prepare a summary.

EDITORIAL SUMMARY: VALIDATION OF DECOMPRESSION TABLES

R.W. Hamilton and Heinz R. Schreiner
with some special advice by David H. Elliott and Russell E. Peterson.

This is a summary and consensus of the Workshop on Validation of Decompression Tables, sponsored by NOAA/NURP and held at Bethesda by the Undersea and Hyperbaric Medical Society, 1987 February 13-14:

Schreiner HR, Hamilton RW. May 1989. Validation of decompression tables. UHMS 74(VAL)1-1-88. Bethesda, MD: Undersea and Hyperbaric Medical Society.

Approaching a consensus

As is evident in the talks and particularly the discussion, the Workshop seemed to be generally agreed on the steps that belong in a table validation process (there were some disagreements about other points!). However, although many principles were discussed (albeit some quite briefly) a coherent and complete pattern was not completely articulated at any time. As both our editorial duty and privilege, we here attempt to distill out of the talks and discussion the essence of a model for the validation of decompression tables. This is not necessarily a condensation of what was said, nor is it a formal consensus, but is what we feel the group was searching for. It should be quite close to what the Workshop would have produced as a consensus or majority viewpoint had we been able to do that in more detail.

The table validation process

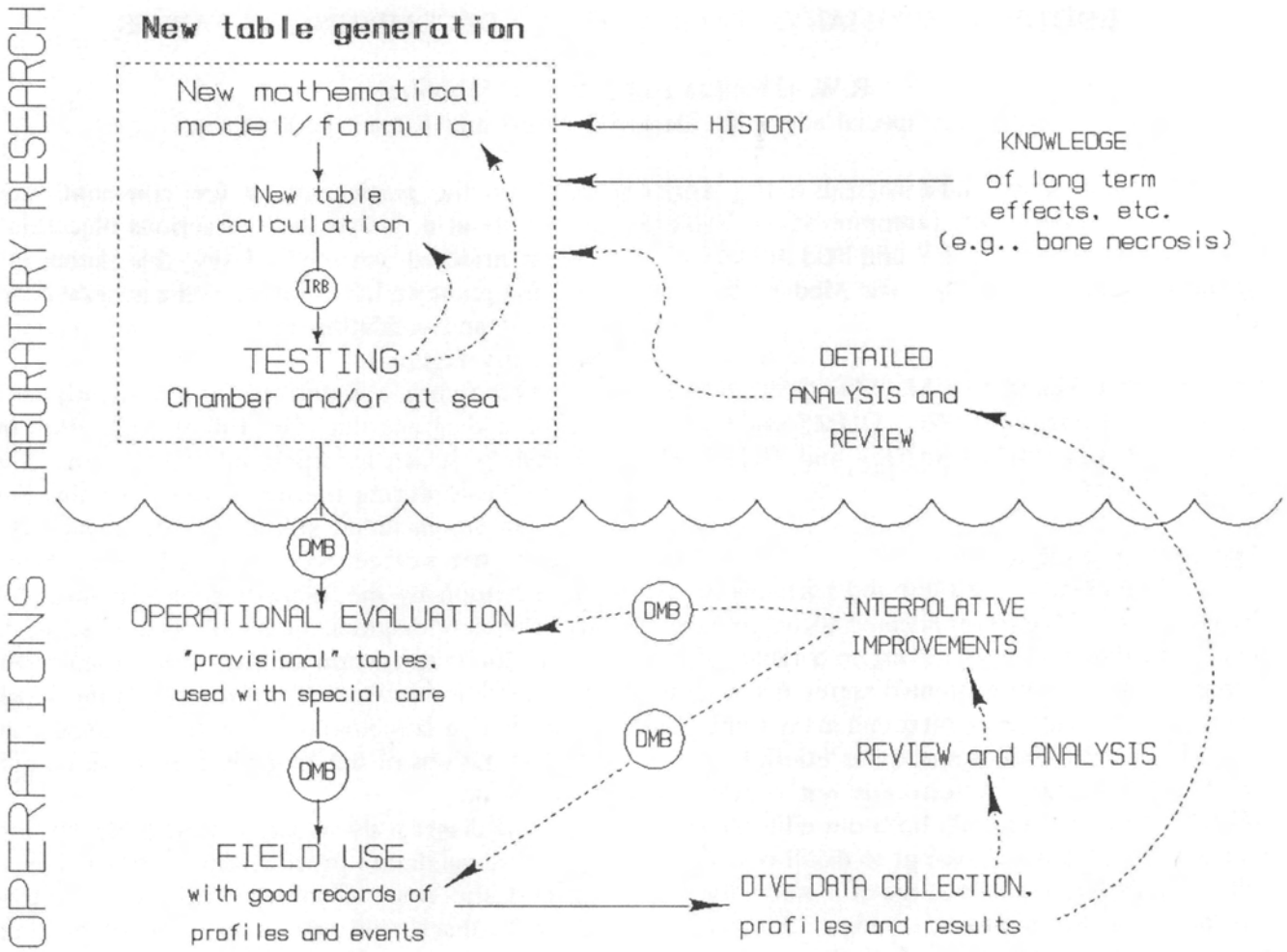
The initial charge to the Workshop was to define the **validation** process and not deal with the earlier steps in the overall process of decompression table **development**. Indeed, the Workshop showed impressive restraint in doing just that, but to put the validation steps in the proper context this summary covers the whole process of decompression table development, with special attention to validation.

The best approach toward a definite consensus that the group did agree on was a sketch made by Dr. David Elliott (Discussion Figure 1) near the end of the last discussion session. This was distributed to the participants, a few comments were made about it, and by lack of serious objection it was considered accepted. Using this sketch as a starting point we have constructed a general development and validation process which is given in Summary Figure 1.

Our figure was derived from a slightly more detailed diagram that Dr. Elliott sent after the workshop, which incorporated some of the comments made during the discussion. For this final drawing we included still more additional information that we feel was expressed and generally agreed upon by the Workshop participants. We use the new diagram, Summary Figure 1, as the fabric for a discussion of the table development and validation process as constructed by the Workshop; it is a combination of current practice and the conclusions of the Workshop as to what ought to be done.

The diagram shows steps in the table development and validation process. Solid arrows show in general the flow of information, dotted arrows show feedback, and arrows with circles on them signify an "approval" step, discussed below.

For purposes of carrying out decompressions, the diagram is divided into two areas by a wavy line that loosely resembles but does not necessarily signify the surface of the sea. The upper part is the research laboratory. **Testing in the laboratory**, which in decompression research generally means simulated dive profiles carried out in a pressure chamber but not limited to that, is **by intent** research, and it is **carried out under medical control**. This means that it conforms to the prevailing standards for human research of the institution conducting the tests. This would imply conformance with the principles of the Declaration of Helsinki. If this is a university operating with funds from the US National Institutes of Health or Department of Defense, it will have an Institutional Review Board (IRB) and a prescribed documentation procedure. Dr. Lanphier has elegantly described this system in his talk, and we need not dwell on the details here. Where proce-



Summary Figure 1. Flow diagram of the decompression table development and validation process. The upper part of the diagram is by intent research and subject to "informed consent" procedures. The lower half is operational, and is considered to be within the job description of the divers. Solid arrows show flow of information, dotted arrows show feedback, and those with circles imply some judgemental approval by the Institutional Review Board (IRB) or the "DMB," a competent authority (board or committee) within the organization conducting the dives; it might be called the "Decompression Monitoring Board."

dures are not so regulated, common ethics and certainly the consensus of this Workshop dictate that the institution nevertheless has the obligation to conform to the Helsinki principles with regard to the informing and protection of the experimental subjects (these principles are found in the frontispiece of any issue of *Undersea Biomedical Research*).

The arrow connecting "new table calculations" with "testing" has the IRB (Institutional Review Board) symbol, indicating that the conduct of these tests, the testing of these new tables, is monitored by the IRB and by implication is carried out in accordance with the ethical principles. If there is no IRB, as in the case of a diving company for example, it is then the responsibility of the institution--the laboratory and the investigators--to ensure that the ethical requirements are met. This also means that the testing or experiments are carried out under medical supervision. Because

the main tenet of ethical human experiments is that the subjects are **volunteers** and that they **understand the risks** involved, this type of control is often referred to as "informed consent." The Workshop used this term to refer to experimental work conducted under these principles.

The diagram shows two **feedback** loops from the testing stage through an analysis step and back to new table calculations or more fundamental changes at the "model" step. Also shown is the fact that the review and analysis process draws on past history--literature, experience of all sorts, all types of information from the past--plus knowledge of long term effects such as bone necrosis and a review of the organization's own dive logs.

The bottom part of the diagram represents "operational" use of decompression tables. Here the work is **by intent not research**, and although it may (and should) have medical coverage, it is **not under medical control**. This is operational work, and the workers are not experimental subjects and what they do in using new tables falls within their **normal job description**.

It should not be inferred that all work in the sea is operational and all that done in chambers is experimental. Some operational testing is carried out in pressure chambers by divers in their normal work, and some testing is carried out at sea using "informed" subjects. The criteria to separate these are intent, medical control, and whether done as a regular part of a job or for the purpose of testing physiological/medical procedures. This distinction is not always clear, however, and some judgement is needed; a proposed method of dealing with it is discussed later.

The first step beyond the laboratory and into the "real world" of field operations is **operational evaluation**, or the use of the **provisional** table. This is normally the first "at-sea" use of a table or procedure, and we would expect it to be a somewhat tighter operation than usual (proper training and supervision, management cognisance, good medical coverage, accurate records keeping, etc.). After a period of "op eval" then the table can be considered to be in normal operational or "field" use.

During either or both of these phases there can be a need for small modifications that represent changes but do not justify going all the way back to the basic model. In a good operation there should also be a collection of dive records that can serve as the experience base for both the small improvements and later modifications to the model and perhaps eventually a new development program. In the diagram the changes are called **interpolative** to note that they should be within the envelope of the validated part of the model or formula, rather than extrapolations outside it which should be done in the research zone.

This describes the table development process as it is presently carried out in some places; it can serve as the skeleton for a similar system which involves no additional steps but defines some new "authorizations" that can, we hope, maintain high ethical standards, reduce the exposure to unrealistic liability, and still allow cost-effective improvements in decompression.

The organization's Decompression Monitoring Board

Specifically in relation to Dr. Elliott's diagram and in other parts of the discussion as well, the Workshop was concerned about how to **cross the line** between laboratory and operations. Mr. Sutterfield made the suggestion that it would probably be considered acceptable practice if the divers in the op eval stage (using the provisional table) were to be volunteers for this work and were to give their informed consent. This would take care of that step (if the divers would do it; some would not), but then how do we decide the next step, when the table is ready for field use? The same questions come up again about how to decide when small changes made in the op eval or field stages are acceptable, and so on.

On the question of when diving is "research" and when it is "operations," it was pointed out by Dr. Peterson that this would be when a **competent authority** says it is. Several other times during the meeting this same idea was mentioned, and it shows on Dr. Elliott's diagram. The point is that some of these steps need to be made with **judgement**, and that should, obviously, in matters of decompression be by an authority that is competent to make decisions about decompression. The authority was felt by most sentiment in the Workshop to be a small **group** or **committee**.

This was further interpreted that this should not be a "government" or even an "international" body, and that no single body could in fact be

competent to pass on all the many matters that might come up in the many places where decompression decisions have to be made. It has to be a group **specific to the organization** doing the decompression development. It is the organization's group, but the makeup was not specified by the Workshop other than that this group should have the competence, the responsibility, and the authority to make these judgments.

In order to be able to add this necessary element to the table validation process we have given it a tentative name, and have included it on the flow chart in Summary Figure 1. The interim name is the institutions "**Decompression Monitoring Board,**" and it shows on the diagram as DMB. The DMB makes the decision when enough testing has been done and when it is ready to go into the operational evaluation stage. The DMB also decides when it is time to consider the tables operationally ready for field use, it decides when interpolative improvements to provisional or operational tables are suitable, and it maintains cognisance of the review process.

The makeup of the DMB is up to the organization, but as an example it might consist of the safety officer, the medical director, a member of top operational management, and the decompression specialist.

Guidelines

Throughout the workshop there were various references to the need for "standards" or perhaps more properly "criteria" or "guidelines" for the table validation process, and there was valid concern that such things might turn out to be inappropriate. The process laid out here is not a standard or even a guideline. It is actually a **snapshot** of how this process really works in some of the more responsible institutions involved in table development and validation. The process used by the U.S. Navy is quite close to this, even though it may not be formally defined as such. The process as discussed here is more than just validation, it actually covers all parts of the decompression table development process of which validation is only a part.

While we (the Workshop) have defined a general process, we have not really worked out how to implement it. To carry on, we do in fact need guidelines. It is important not to call these "standards" because of the legislative implications and potential for misunderstanding. The guidelines should probably be formulated by a group similar to this Workshop but smaller, and should if possible be designed to be universally applicable.

Guidelines are needed for several points in the validation process. Presuming a plan such as this one is to be used, an important place to start is in how an institution or diving organization should develop and manage the **DMB.** This should include criteria for selecting the members, defining its scope of responsibility and authority, and how it is to go about making the various decisions. (A better name might be suggested as well.)

Some specifications ought to be given for deciding when it is time to move a new table into its next phase, such as operational evaluation and field use. Principles for conducting operational evaluation dives ("with special care") that can be incorporated into the practice of a wide variety of organizations should be laid out, including such things as quality of supervision, medical coverage, treatment capabilities, monitoring, and documentation. There should be guidelines for how to make and evaluate the "interpolative improvements." Since much may rely on data from dive records, what data should be collected and how it should be handled needs to be defined, as well as how to perform the review and analysis of dive data.

These refer to the operational phase. Some special guidelines also would be helpful for the organization not already under institutional review rules, to enable them to select and use a "human use board" (their own IRB) in an ethical yet effective way. Along with this it would be nice to have help in bringing in the essential experience about long term effects and historical experience for use when designing new models and new tables. Criteria for how to perform testing and how to assess when testing is adequate are needed. How the IRB and DMB relate and possibly overlap should be stated.

If a set of guidelines (or a consensus document) that meets the above criteria can be developed, it could have a beneficial effect on litigation in the US. A diving company or other organization that might gain from developing better decompression tables would have a "standard" to follow that would--if they could demonstrate that every-

thing had been done according to the guidelines--establish that they were in conformance with accepted practice.

Summary and next steps

The job is not complete, but this Workshop has made a good start. We have defined an exemplary pattern for the ethical development of decompression tables, including the use of past experience to make a model and calculate new tables, accepted practice for initial testing, and a mechanism of approval to move the tested tables forward to initial operational evaluation and finally normal field use. Steps requiring judgement are to be made by an authoritative group designated by the organization. Feedback loops allow for corrections at several steps along the way, again with approval by the diving organization's experts, and meaningful collection and review of data as it accumulates is called for.

What is needed next is a set of guidelines for managing this process, including procedures for the formation and management of the responsible monitoring groups, methods for collection, review and analysis of data, and criteria for determining when it is appropriate to take the various steps in the process. Government control or approval is not indicated, but government funding of the development of the guidelines as a research and development task would make good sense.