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VALIDATION OF DECOMPRESSION TABLES

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EDITORIAL SUMMARY: VALIDATION OF DECOMPRESSION TABLES

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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:

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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

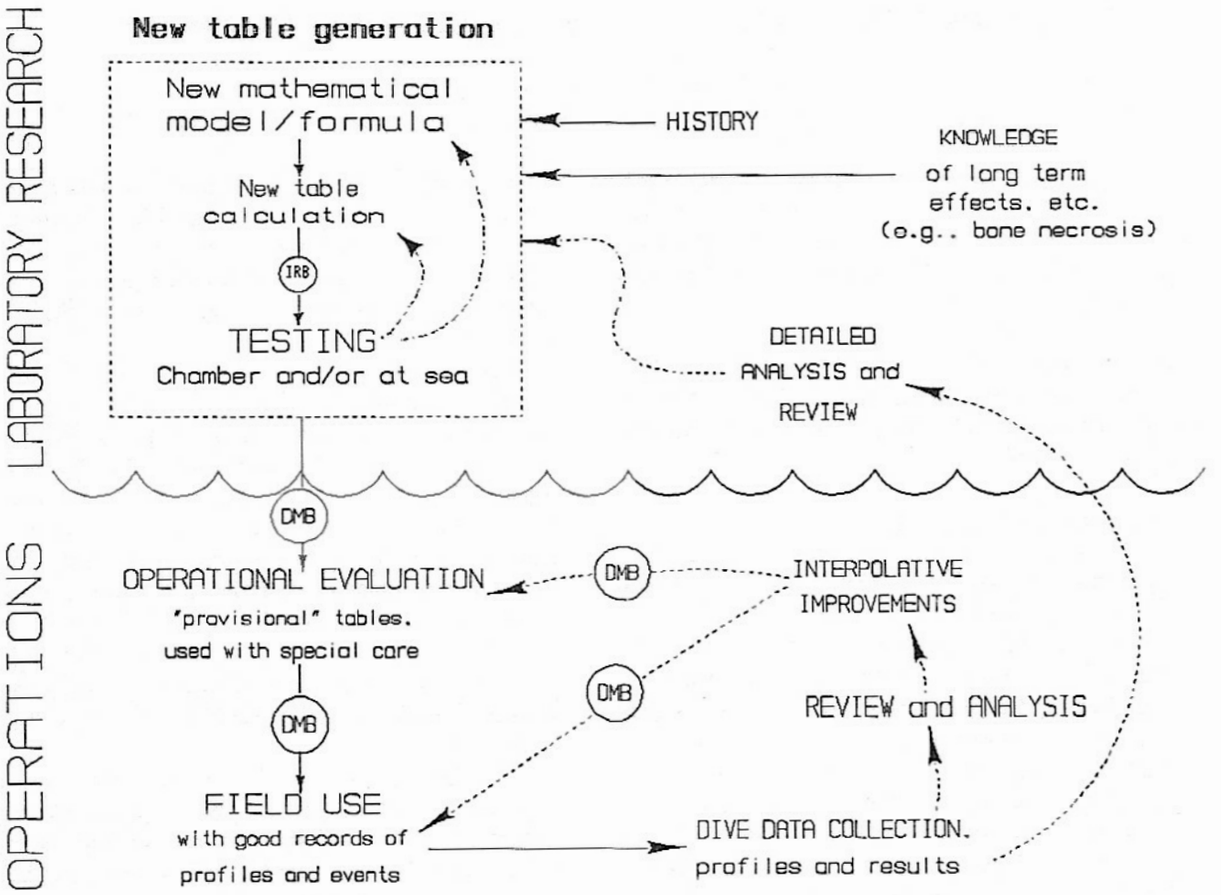
The initial charge to the Workshop was to define the **validation** process and not deal with the earlier steps in the overall process of decompression table **development**. Indeed, the Workshop showed impressive restraint in doing just that, but to put the validation steps in the proper context this 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.