Verification, Validation and Accreditation of Diving Decompression Tables

Navy Experimental Diving Unit
Panama City, FL

Naval Modeling and Simulation Management Office Validation, Verification and Accreditation Technical Working Group (NAVMSMO VV&A TWG)

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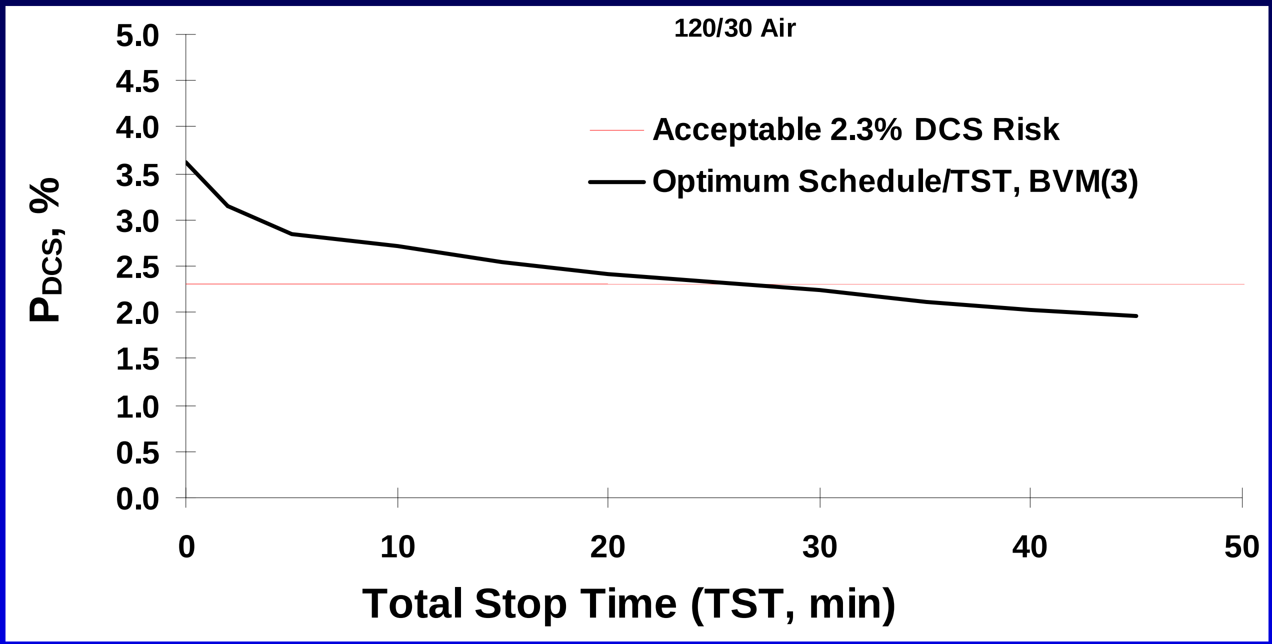
Problem: Overview

- Increase the efficiency and safety of decompression procedures for divers based on ever-increasing empirical information and improved theoretical understanding:
  - Provide increased operational flexibility in the face of changing field conditions and experience through simplified procedures that share a common theoretical/methodological foundation.
    - Combat Swimmer support (complex multi-level and repetitive diving profiles)
    - Aggressive use of oxygen to increase no-stop limits and decrease decompression obligations
    - Decrease surface interval times
    - Flying after diving; Diving at altitude

Problem: Overview (*continued*)

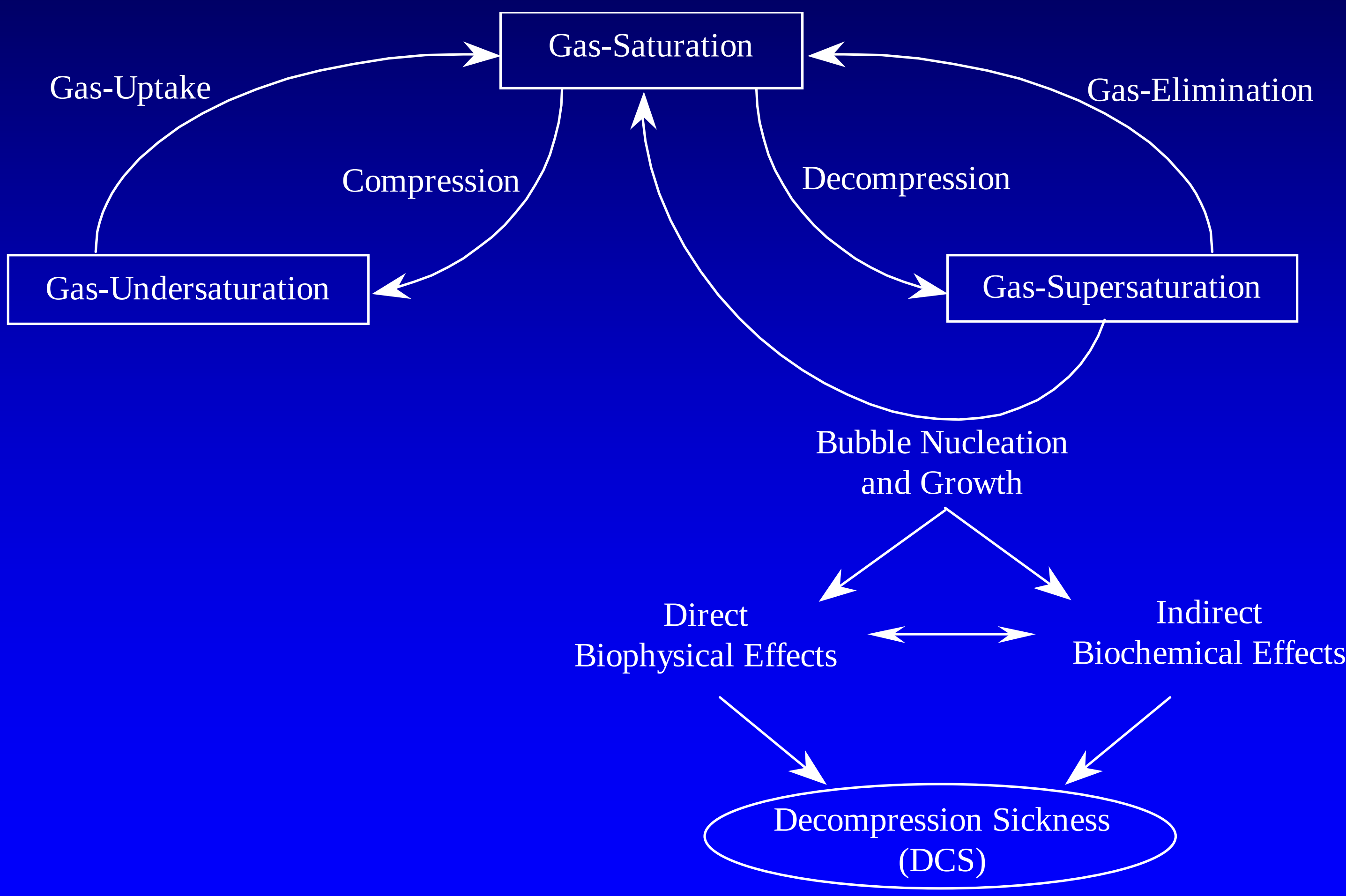


Increasing TST ⇒

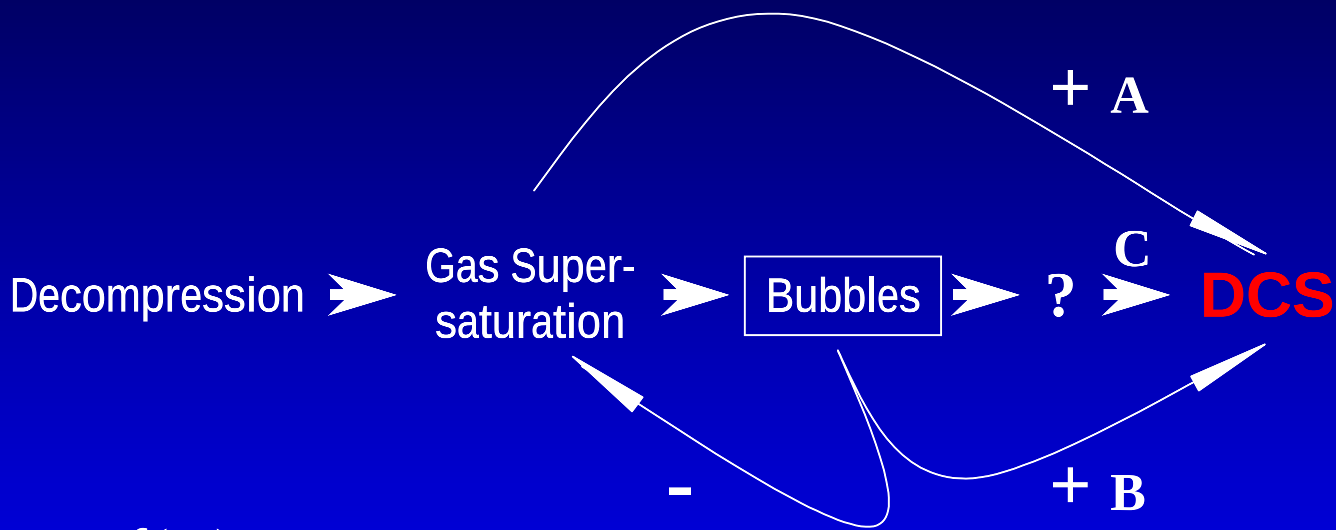
- **Decreasing DCS risk**
- **Decreased efficiency (defined as BT/TDT)**
- **Increased risks of "other" (e.g., thermal exposure, O_2 toxicity, hazardous marine life, explosion, etc.)**

<u>Objective</u>: Deliver decompression tables that prescribe schedules for individual dives that incur DCS risks considered acceptable by the end-user in consideration of his or her other operational risks.

DCS Model Paradigm



Expression of Outcome, P_{DCS}



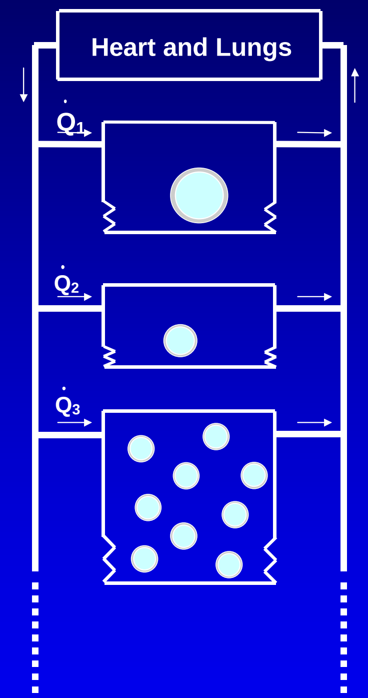
$P_{DCS} = f(X)$

A) X = inert gas content
B) X = bubble volume
C) X = bubble-induced process

↑ Quantified using theoretical/conceptual construct

DCS Model Conceptual Schematic

n-parallel perfused compartment model of whole body (3 compartments shown)



- Gas exchange, bubble nucleation, and bubble dynamics equations are readily written for this system to solve various explicit $P_{DCS} = f(X)$ formulations.

Model Developmental Objectives

- Internally consistent mathematical representations of etiological processes thought to govern decompression outcomes:
  - as theoretically complete and correct as possible, but;
  - computationally tractable for application in the compute-intensive analytic environment of probabilistic, maximum likelihood modeling.
  - Motivation:
    - more accurate description of outcomes in ever more diverse and complex types of pressure and respired gas profiles
    - accommodation of additional governing factors; e.g., exercise and thermal effects.
    - reliable extrapolation.

Verification

Verification: to establish the truth, accuracy, or reality of

- True “verification” of models used to compute decompression schedules has so far proven impossible.
  - Gas bubbles are routinely observed at various anatomic sites in decompressed individuals, but the bubble or bubbles that cause DCS have never been observed.
- We never-the-less cling to our paradigm in order to proceed.

Verification

- The process by which we ensure that a model, *whether true and complete or not*, provides its best-possible accounting of observable reality.
- Achieved by systematic adjustment of model parameters values to maximize conformance of model-predicted P_{DCS} with observed incidences.
- Methods: Likelihood maximization and model goodness-of-fit assessments.

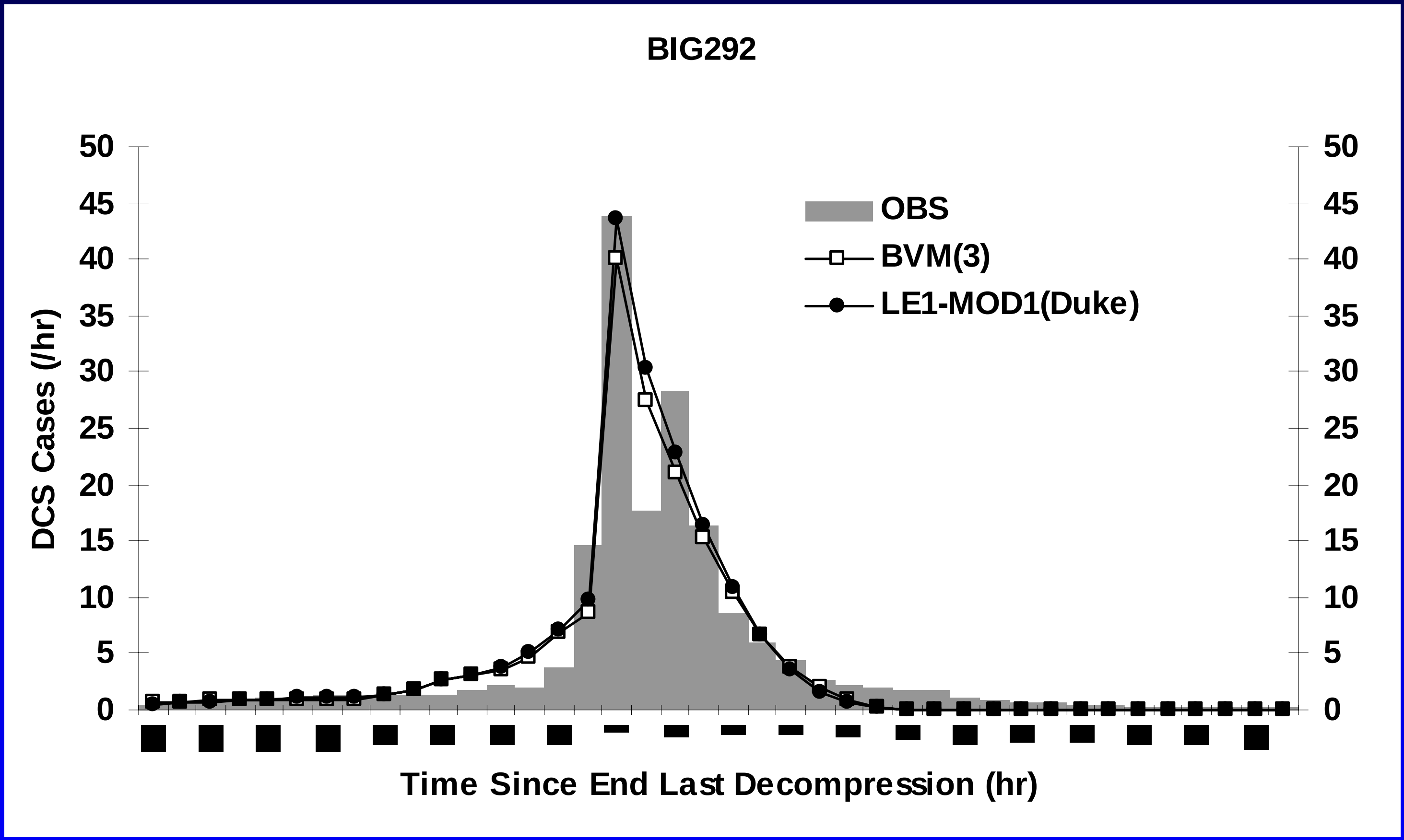
Likelihood Maximization

- Likelihood ≡ probability of *observed* outcome under a particular model.
  - Maximum when model-predicted outcome equals observed outcome.
- Likelihood maximization yields model best-fit to a given body of data.
  - Problem:
    - # adjustable parameters, and hence model complexity, is limited by data sample size.
  - Solution:
    - Meta-analysis: combination of relevant data from a variety of sources under a given model.

Goodness-of-fit Assessment and Model Selection

- Comparing Different Candidate Models
  - Informal Comparisons Using LL_{max} values
  - Formal Tests of Parameter Significance
    - Wald Test
    - Likelihood Ratio Tests
      - Nested Models
      - Nearly Nested Models: The Approximate Likelihood Ratio Test
  - Akaike Information Criterion (AIC)
- Comparing Estimated and Observed Probability Density Distributions
- Comparing Incidence-Only Model Predictions to Observed Incidences
  - Quantitative: Chi-Square Tests
    - Group-Specific
    - Global
  - Qualitative: Graphical Comparisons

Goodness-of-fit Assessment: Example



Observed and model-estimated DCS occurrence density distributions for model calibration data of 3322 air and nitrox man-dives.

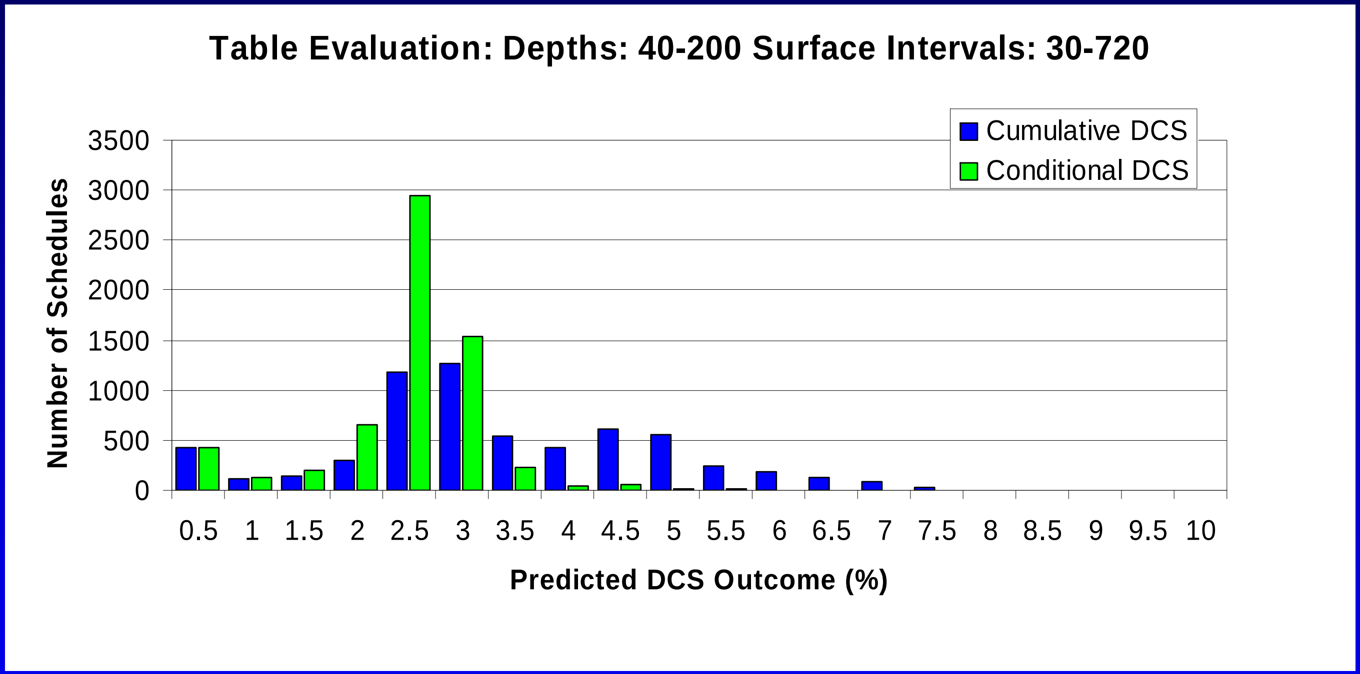
Validation

- Validate:
  - to support or corroborate on a sound or authoritative basis; confirm;
  - assess goodness-of-fit of model on observations where model is theoretically known and no parameter estimation is performed;
  - **Confirm that model produces schedules that meet but do not exceed *a priori* acceptable risk(s).**
    - **Here, we evaluate products of the "verified" model.**

Schedule Selection

- Individual schedules *vs*. tables.
  - Random assembly of schedules and test.
    - Theoretical. Use verified/validated model to evaluate risks of hypothetical profiles assembled from the tables. Large numbers of different profiles are readily examined.
    - Man trials.
      - Chamber trials. # trials severely limited by temporal and fiscal constraints.
      - Field trials. (Carefully monitored and circumscribed use of new procedures in field operations can be undertaken without prior chamber trials in cases when the new procedures are considered to be an interpolation within existing proven experience.)

Theoretical Evaluation: Example



Frequency distribution of the estimated DCS risks of 6,250 MK 16 MOD 1 He-O_2 dive profiles randomly constructed from new MK 16 MOD 1 He-O_2 decompression tables. The distribution of conditional DCS probabilities includes only the maximum conditional DCS probability from the dives in each repetitive dive profile.

Man Trial Design

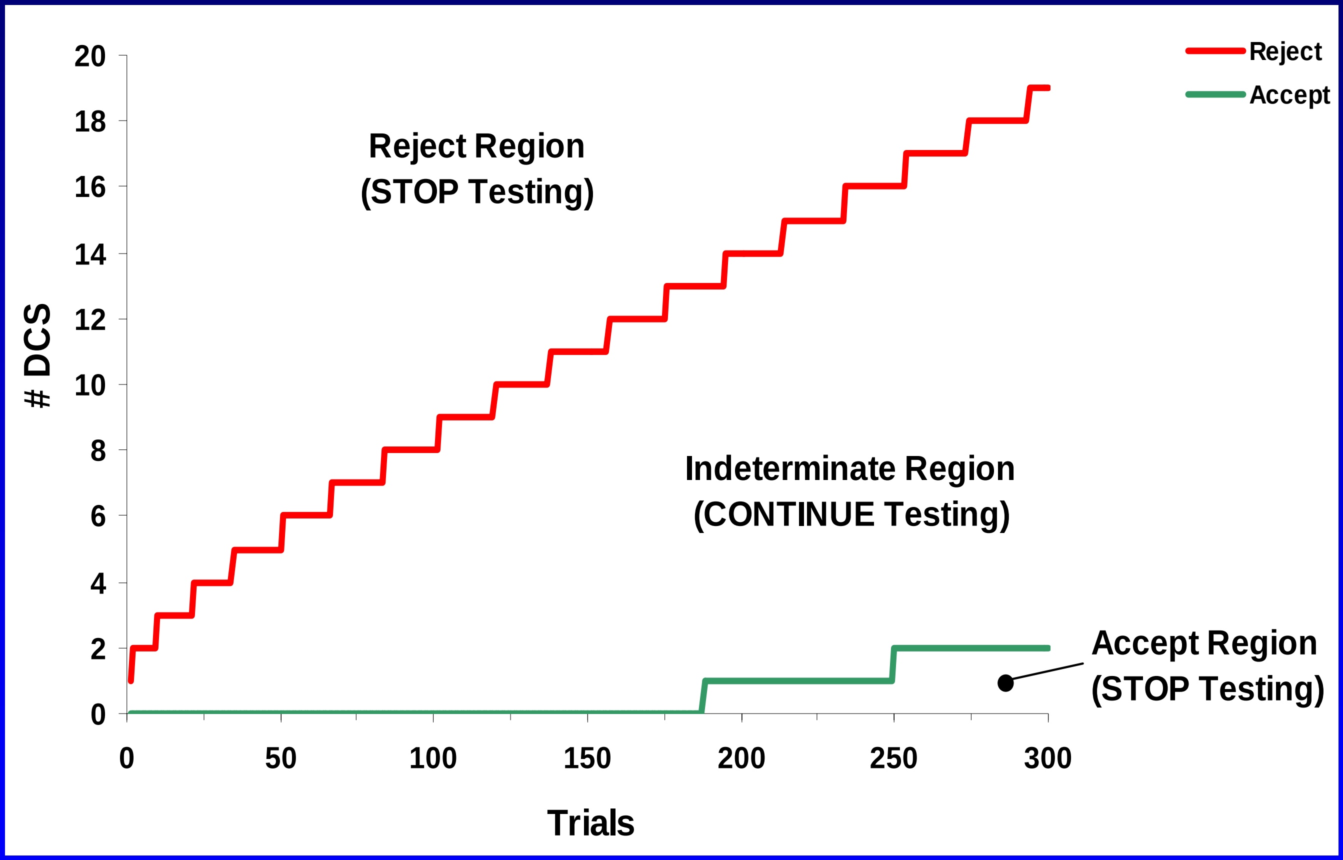
- Issues:
  - Profile Selection (What dive profiles do we test?)
    - Random selection from pool of randomly-assembled profiles.
  - Trial "Stopping Rules" or "Accept/Reject Criteria" (How do we limit risks to subjects as they dive the test profiles?)
    - Binomial
      - Confidence limits and hypothesis tests
    - Likelihood
  - Sample Size and Power (How many profiles do we test?)
    - Acceptable DCS risks are low, requiring large sample sizes for statistically meaningful results.
    - Time and funding constraints limit sample sizes.

Trial Stopping Rules

- Seek to stop testing if and when information has accrued to support a statistical decision at a given level of confidence. E.g.:
  - **Reject** as excessively risky when 95% confident that true risk of procedure exceeds 4%.
  - **Accept** when 95% confident that true risk of procedure is less than 2%.
- Essence of Sequential Trial Design.
  - Minimizes # subjects exposed to excessively risky test procedures.
  - Minimizes # unnecessary tests of acceptable procedures.

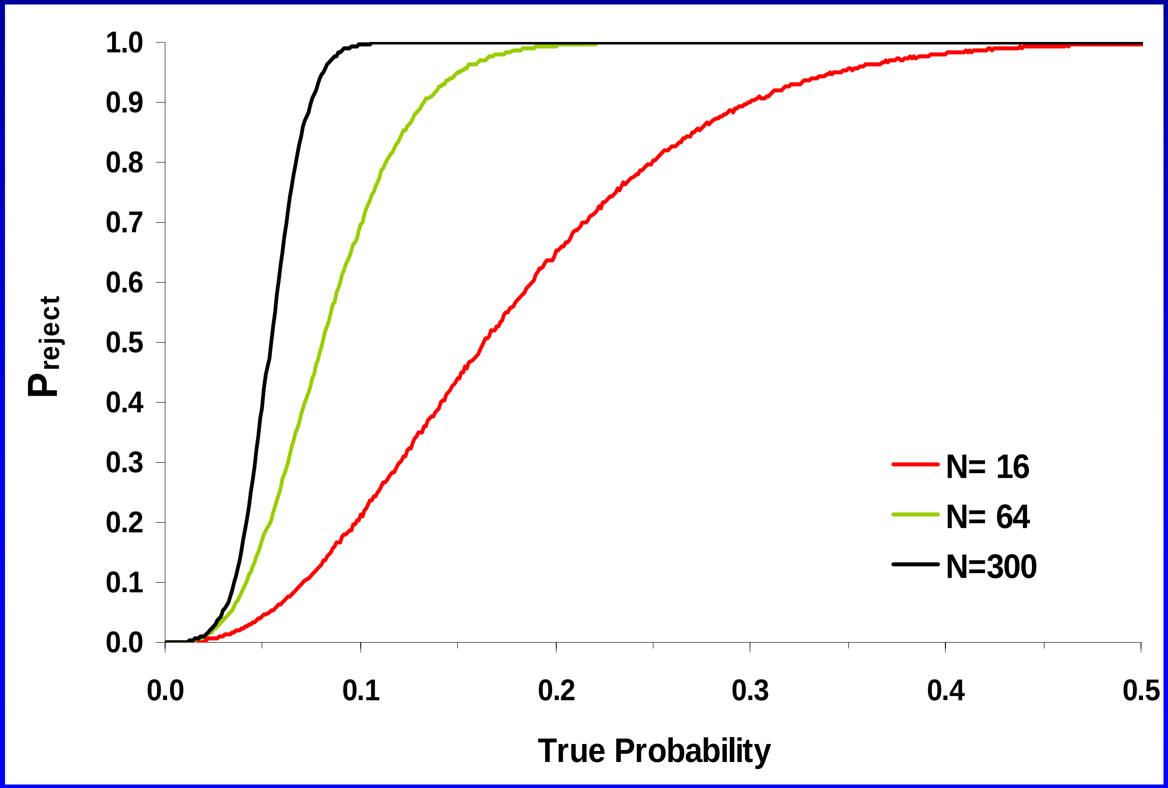
Sequential Trial Design

- Reject/accept rules and binomial theorem are used to prescribe decision-making as trial results accumulate.



Sample Size and Power

- Monte Carlo simulations are used to assess probability of rejecting an intrinsically unacceptable procedure with given stopping rules.
- Reasonable P_{reject} of an intrinsically low-risk procedure requires large sample size, N.



Validation Success

- Assessed using same statistical tools used in model development and verification.
  - Hypothesis tests w/ confidence limits.
  - Likelihood ratio tests.
- “Face validity.” Do prospective new tables prescribe schedules with decompression times that conform with end-user expectations based on relevant previous experience?

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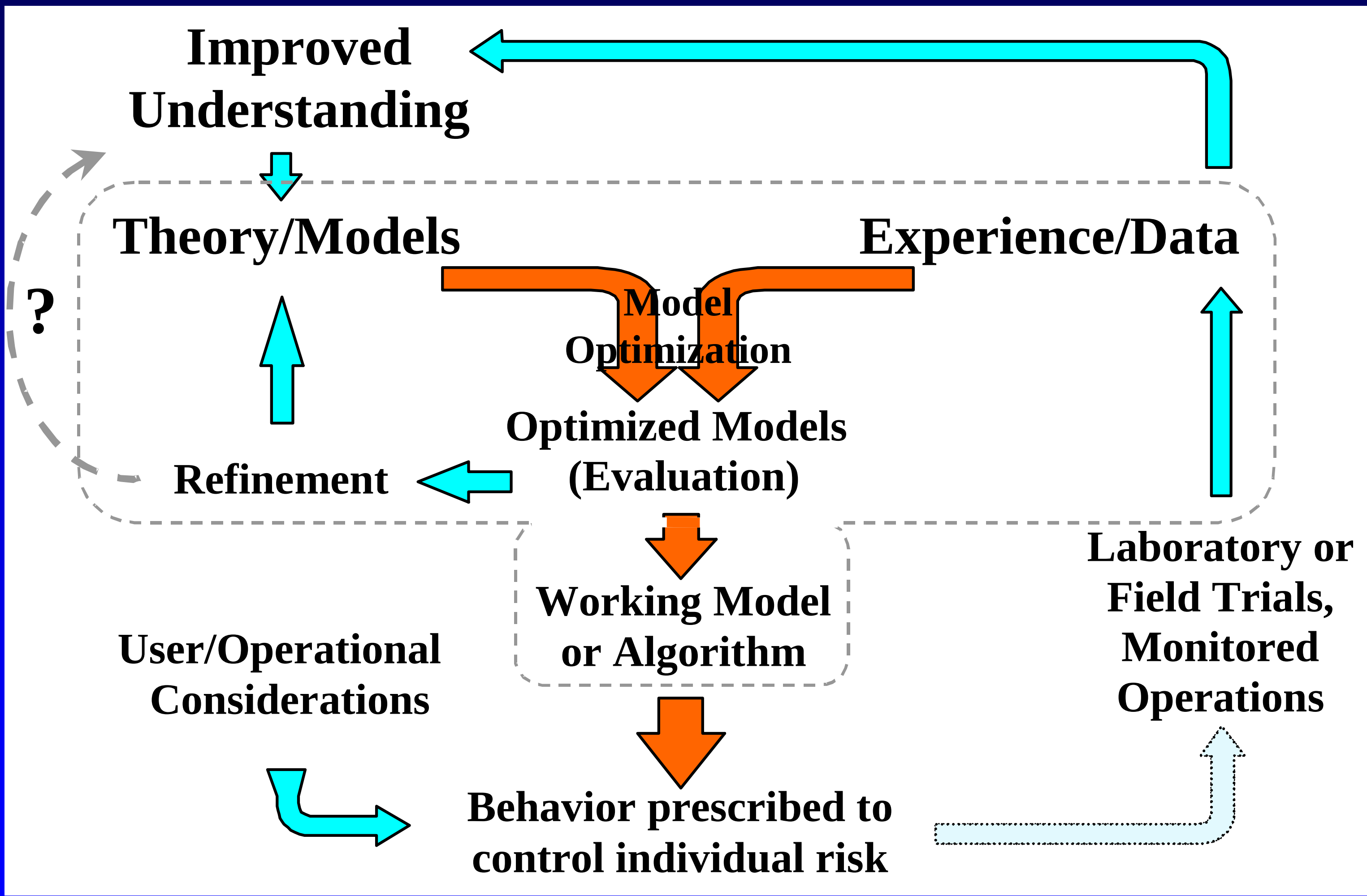
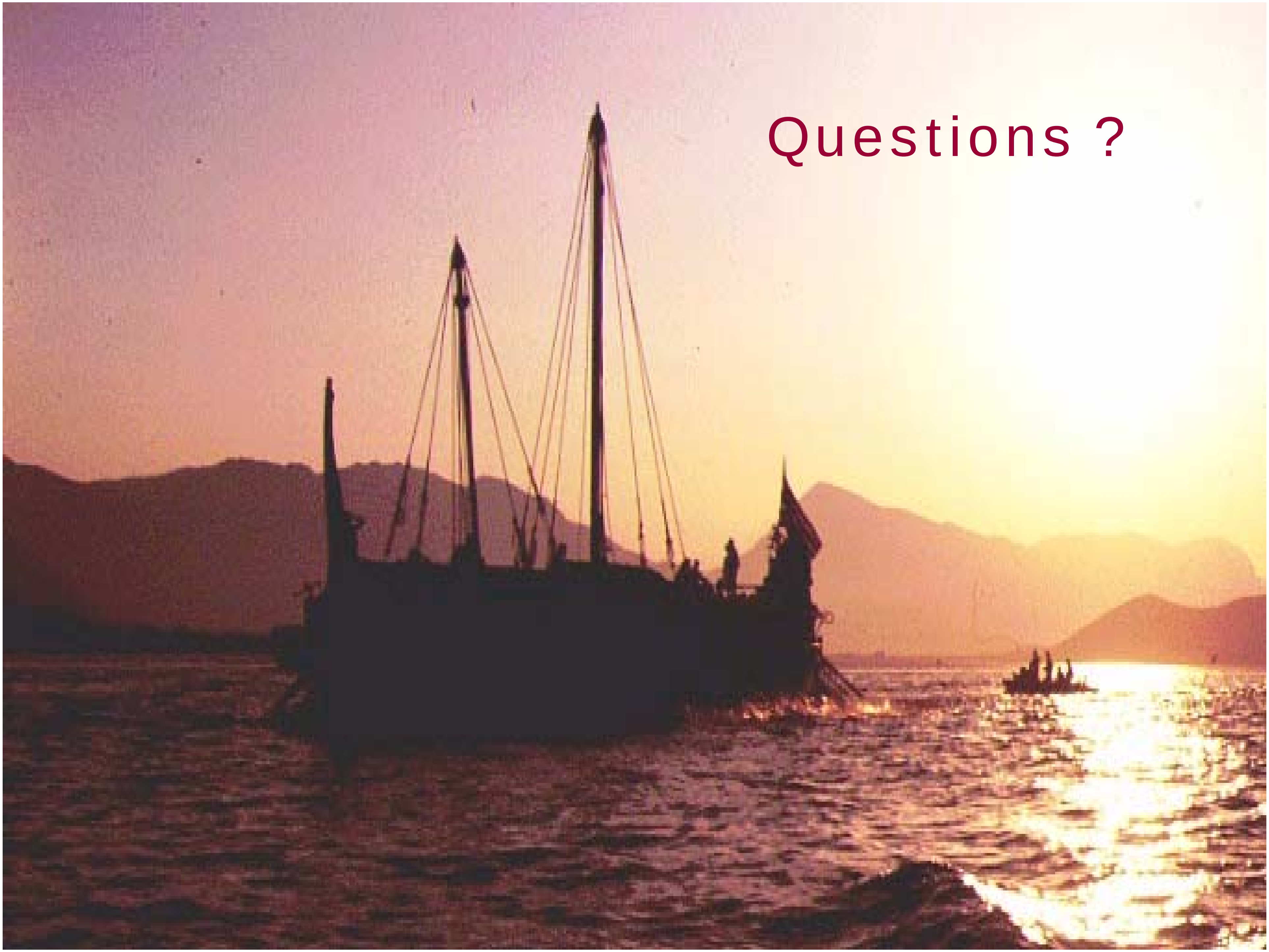
Accreditation

- Review and endorsement by:
  - CO, NEDU.
  - (Sponsoring/end-user community; EOD, SPECWAR, etc.)
  - Supervisor of Diving, NAVSEA OOC3.
  - Supervisor of Salvage and Diving, NAVSEA OOC.
- Incorporation into U. S. Navy Diving Manual for fleet use.

Process Summary




Questions ?